PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Jonathan Stinson**
Application No.:	**10/037036**
Filed:	**October 25, 2001**
For:	**Balloon Expandable Polymer Stent With Reduced Elastic Recoil**
Examiner:	**Vi X Nguyen**
Group Art Unit:	**3734**

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2B-9919-US01

THIRD APPEAL BRIEF

This is an Appeal Brief for the above-identified application in which pending claims 1 – 11, 15 – 24, and 26 – 32 were rejected in an Office Action dated June 30, 2008.

A Notice of Appeal is being filed with this Appeal Brief.

This is a Third appeal in this application so this brief is being filed with a reduced fee payment.

The Commissioner is authorized to charge Deposit Account No. 22-0350 for any other fees which may be due with this Appeal Brief.

(i) Real Party in Interest

The Application is assigned to Boston Scientific Scimed, Inc., formerly known as Scimed Life Systems, Inc., One SciMed Place, Maple Grove, Minnesota 55311-1566, a Minnesota corporation and a subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts 01760-1537, a Delaware Corporation.

(ii) Related Appeals and Interferences

No related interferences or Appeals are currently pending.

In this application two prior Appeals have already been taken (First Appeal 1: Notice of Appeal filed 12/20/2004; Appeal Brief filed 2/16/2005; Second Appeal: Notice of Appeal filed 9/12/07, Appeal Brief filed 11/13/07 (mail room dates per PAIR). After the Appeal Brief in the First Appeal was filed the final Action was withdrawn (3/3/2008 Requirement for Restriction/Election); and prosecution was reopened without filing an Examiner's Answer. After the Appeal Brief was filed in the Second Appeal prosecution was reopened to allegedly to institute a new ground of rejection (6/30/2008 Office Action). Consequently there is no prior Board Decision.

The outstanding rejections only present questions of patentability substantially cumulative of those presented in the prior appeals. Consequently in this application the applicant has been arbitrarily and capriciously deprived of its statutory right to appeal under 35 USC §134 in violation of the Administrative Procedure Act. A defensive petition is being concurrently filed with this Brief to insist that the Examiner's response be confined to filing an Answer or allowance of the application.

(iii) Status of the Claims

Claims 1-32 have been presented in the application. Claims 12 – 14 were canceled in an amendment filed August 1, 2006. Claim 25 was canceled in an amendment filed November 15, 2006.

Claims 1 – 11, 15 – 24, and 26 – 32 are pending.

No claim has been allowed.

Claims 1 – 11, 15 – 24, and 26 – 32 were rejected in an Office Action mailed June 30, 2008.

Claims 1 – 11, 15 – 24, and 26 – 32 and are the subject of this Appeal.

(iv) Status of Amendments

No amendments have been filed after the Final Rejection dated June 30, 2008.

(v) Summary of Claimed Subject Matter

A summary of the independent claims, as required by 37 C.F.R. § 41.37(c)(1)(v), and a non-limiting listing of locations where support may be found {braced citations} is provided as follows:

Claim 1 is directed toward a process comprising steps "a" – "c". Step "a" includes forming a generally tubular stent {page 5, lines 4 – 9} of polymer material {page 6, lines 3 – 15}. Step "b" includes radially expanding the stent to produce an expanded diameter stent. {Page 5, lines 10 – 20}. Step "c" includes annealing the expanded diameter stent to shrink its diameter to a reduced diameter. {Page 5, lines 21 – 27}. Steps "a" – "c" are all performed prior to deployment of the stent in a body. {Page 10, lines 18-22}.

Claim 15 is directed toward a process comprising steps "a" – "c". Step "a" includes forming a generally tubular article {page 5, lines 4 – 9; page 12, lines 6 – 9} of polymeric material {page 6, lines 3 – 15}. Step "b" includes radially expanding the article to produce an expanded diameter article. {Page 5, lines 10 – 20}. Step "c" includes annealing the expanded diameter article to shrink its diameter to a reduced diameter. {Page 5, lines 21 – 27}. Steps "a" – "c" are all performed prior to deployment of the tubular article in a body. {Page 10, lines 18-22}. And, at least one time steps "b" and "c" are repeated in sequence on the tubular article. {Page 5, lines 25 – 27}

Claim 17 is directed toward a process comprising steps "a" – "c". Step "a" includes forming a generally tubular article {page 5, lines 4 – 9; page 12, lines 6 – 9} of polymeric material {page 6, lines 3 – 15}. Step "b" includes radially expanding the article to produce an expanded diameter article. {Page 5, lines 10 – 20}. Step "c" includes annealing the expanded diameter article to shrink its diameter to a reduced diameter. {Page 5, lines 21 – 27}. Steps "a" – "c" are all performed prior to deployment of the tubular article in a body. {Page 10, lines 18-22}. The polymer material is a biodegradable polymer. {Original claim 17; page 6, line 3 – page 7, line 2}

Claim 21 is directed toward a process comprising steps "a" – "d". Step "a" includes forming a tube {page 5, lines 4 – 9; page 12, lines 6 – 9} of polymeric material {page 6, lines 3 – 15}. Step "b" includes radially expanding the tube to produce an expanded diameter tube. {Page 5, lines 10 – 20; page 12, lines 6 – 9}. Step "c" includes annealing the expanded diameter tube to shrink its diameter to a reduced diameter. {Page 5, lines 21 – 27; page 12, lines 6 – 9}. Step "d" includes forming a stent from the annealed tube. {Page 12, lines 6 – 9} Steps "a" – "d" are all performed prior to deployment of the stent in a body. {Page 10, lines 18-22}.

Claim 26 is directed toward a process comprising steps "a" – "d". Step "a" includes forming a generally tubular article. {Page 5, lines 4 – 9; page 12, lines 6 – 9}. Step "b" includes radially expanding the tubular article to produce an expanded diameter tubular article. {Page 5, lines 10 – 20}. Step "c" includes annealing the expanded diameter tubular article to shrink its diameter to a reduced diameter. {Page 5, lines 21 – 27}. Step "d" includes forming the tubular article as a stent with a pattern of perforations therein. {Page 12, lines 6 – 9}.

(vi) Grounds of Rejection to be Reviewed on Appeal

I. Whether the Examiner erred in rejecting claims 1, 15, 17 and 21, 32 under 35 U.S.C. § 102(e) as being anticipated by Stinson, US 6,719,934.

II. Whether the Examiner erred in rejecting claims 1-11, 15-24 and 26-32 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,670,161 to Healy et al. (hereafter "Healy") in view of U.S. Patent No. 4,816,029 to Penny III et al (hereafter "Penny").

(vii) Arguments

I. The Invention

The invention provides novel techniques by which the molecular orientation of a formed stent or a tubular stent preform can be improved to increase hoop-wise orientation. The process is particularly suited to balloon expandable polymer stents. Such stents typically have suffered from high elastic recoil after release of balloon inflation pressure [p. 4, lns. 14-23]. The processes of all the independent claims involve radial expansion of a tubular article or formed stent and annealing of the expanded diameter article to shrink its diameter.

The purpose of the radial expansion step is to cause the molecular structure of the polymer to orient itself around the hoop, stretching causing molecular alignment in the direction of the elongation and increasing strength in the direction of orientation [p.8, ln.22-29]. The purpose of the annealing/shrinking step is to reduce or eliminate residual elastic stresses and to shrink the stent to size for deployment [p.9, ln.15-21].

II. Applicable Law

Anticipation under 35 U.S.C. Section 102(e) requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co.* , 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); *In re Robertson*, 49 USPQ2d 1949 (Fed. Cir. 1999). The Stinson '934 patent does not anticipate any of claims 1, 15 , 17 and 21.

The framework for the objective analysis of obviousness under 35 U.S.C. 103 is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Obviousness is a question of law based on underlying factual inquiries. The factual inquiries are as follows:

(A) Ascertaining the scope and content of the prior art;

(B) Ascertaining the differences between the claimed invention and the prior art; and
(C) Resolving the level of ordinary skill in the pertinent art.

Evidence pertaining to considerations as commercial success, long felt but unsolved needs, failure of others, etc., must also be considered when present.

The Supreme Court in *KSR International Co. v. Teleflex Inc.,* 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007) requires that the analysis supporting a rejection under 35 U.S.C. 103 be made explicit. Quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), the KSR decision states: "'[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *KSR,* 550 U.S. at ___, 82 USPQ2d at 1396.

When determining obviousness, based on a combination of references the prior art must be considered as a whole, without the benefit of impermissible hindsight vision afforded by the claimed invention. The prior art must be applied in the context of their significance to a technician at the time the invention was made, without knowledge of the solution. Taking into account the evidence of common knowledge and the common sense of the skilled person, there must be some evidence of a suggestion, teaching or motivation that would have led the skilled person to produce the invention as claimed. *In re Translogic Technology Inc.*, 84 USPQ2D 1929, 1937 (Fed. Cir. 2007); *Ortho-Mcneil Pharmaceutical Inc. v. Mylan Laboratories Inc.* 86 USPQ2D 1196, 1201-1202 (Fed. Cir. 2008).

It is impermissible, simply to engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template, picking and choosing among isolated disclosures in the various documents to supply elements to fill the gaps. MPEP 2142, discussing

the legal concept of *prima facie* obviousness articulates how the obviousness determination is to be made:

> To reach a proper determination under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. Knowledge of applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

III. The Rejections

A. The Examiner Erred in Rejecting Claims 1, 15, 17 and 21, under 35 U.S.C. § 102(e) as Anticipated by Stinson, US 6,719,934.

1. Arguments Applicable to Each of Claims 1, 15 , 17 and 21

Stinson US 6,719,934 (Stinson '934, Exhibit A) is a division of US 6,245,103 (Stinson '103, Exhibit B) which was cited as anticipating in the First Appeal (See Appeal Brief filed 2/16/2005, Exhibit C). Consequently the issue of anticipation is identical and was already conceded when the prior rejection on Stinson US '103 was withdrawn (see 3/3/2008 Requirement for Restriction/Election, Exhibit F).

The Examiner has indicated no "new light" that would indicate that would justify the reintroduction of a rejection that had already been conceded in this case after an appeal. The Examiner had a full and fair opportunity to justify the rejection to the Board three years ago. Withdrawing the rejection and then re-imposing it three years later, when reopening prosecution after appeal a second time, substantially interfered with the applicant's statutory right of review

under 35 USC §134 (a) without any good cause. The Kafkaesque circular examination to which this application has been subjected withdrawing finality but reinstituting rejections that are not substantially different from those previously taken on appeal is arbitrary and capricious in violation of the Administrative Procedure Act and violates Constitutional Due Process. At least for these reasons the rejection should be reversed.

Regarding Stinson '934 the Examiner contends this time:

> Stinson discloses in figs 7-10 and 14, col. 5, lines 27-41, col. 7, lines 40-67 and col 8, lines 1-22, a process for forming a stent having the limitations of the above listed claims, including: the process comprises the step of forming a tubular stent of the polymer material: the stent radially expanding to produce an expanded diameter stent, and at least one time repeating of steps a-b are all performed prior to deployment of the stent in a body, ***but Healy [sic.] is silent regarding the step of annealing the expanded diameter stent or tubular article to shrink its diameter to a reduced diameter***..
>
> ***Stinson further discloses annealing the expanded diameter stent to shrink its diameter to a reduced diameter*** (see col .25, lines 58-67, col. 26, lines 1-9).

(6/30/08 Action, page 2, emphasis added)

This statement is confusing as to whether the Examiner recognizes that Stinson doesn't disclose annealing an expanded diameter stent to shrink it to a reduced diameter or whether the Examiner contends it does. The latter contention is clearly wrong.

Stinson '934 discloses polymer stents, but the process employed and the products formed are very different from the inventions of claims 1-23 of the present application. The Stinson stents are formed by braiding polymer fibers onto a mandrel and then annealing the braided stent onto a second mandrel of smaller diameter. After the annealing step the stent is stretched longitudinally to a further reduced diameter at which it is delivered. Upon delivery, the stent will *self-expand* to a deployed diameter less than the annealed diameter. The difference

between the braid mandrel diameter and the anneal mandrel diameter can be varied to give a desired deployed diameter within a predetermined range.

As recited in independent claim 1, the "expanded diameter stent," is the product of a radial expansion step (b) performed on the already formed stent . It is this "expanded diameter stent" that is subjected to the annealing step (c), not the stent as formed. This is made absolutely clear in step (c) both from the word "then" in the lead-in to step (c) and in step (c)'s the reference to "the expanded diameter stent," which necessitates that we treat the product of step (b) as the starting point for step (c). This is elementary method claim language. There is nothing tricky about the proper construction of this claim language.

The stent of the Stinson '934 patent is annealed from the stent diameter as formed, not from a "radially expanded diameter." The Stinson '934 patent stent is not subjected to a radial expansion step until it is deployed, or in the case of the tests discussed e.g. in col. 16 when it is subjected to testing to determine deployed diameter and radial force. No annealing step takes place after such radial expansion. The stent of the Stinson '934 patent is annealed before radial expansion occurs. The Stinson '934 patent sequence described at col. 5, lines 36-41:

> … make the stent at a particular diameter (A), anneal the stent at a smaller diameter (B), and deploy the stent from a delivery system of diameter (C) whereby the stent will be "programmed" to self-expand to a desired implant diameter (D). The relationship between the diameters is A>B>D>C.

In this sequence diameter D is the only diameter that is achieved by a radial expansion step and hence the only "radially expanded" diameter. Diameter D is achieved after the annealing step has been performed. Therefore the Stinson '934 patent does not anticipate the process of claim 1.

A parallel construction applies to the article or tube forming steps of independent claims 15, 17 and 21. Therefore the Stinson patent does not anticipate these claims.

At least for the reasons just given the anticipation rejection of claims 1, 15 , 17 and 21 should be reversed.

2. Additional argument for claim 15 - Repetition of the Radial Expansion and Annealing Steps in Sequence

Claim 15 further requires repetition of steps (b) and (c) at least one time in sequence. The Examiner apparently contends that the same passages of the Stinson patent show this. The applicant has no idea what the Examiner is thinking. The Stinson patent does not show repetition of radial expansion and subsequent annealing steps on a formed stent. At least for this additional reason the anticipation rejection of claim 15 should be reversed.

3. Additional Argument for Claim 21 - Stent Pattern Formed From a Tube That Has First Been Subjected To Sequential Radially Expansion and Annealing Steps

Independent claim 21 recites a process sequence in which a polymer tube is formed, radially expanded, the radially expanded tube is annealed, ***and subsequently*** a stent is formed ***from the annealed tube***. That is, the stent pattern is provided ***after*** the tube has been both b) radially expanded and c) annealed at least one time. (This may be accomplished, for instance, by machining or etching the tube after the steps b) and c) have been performed).

The Stinson patent does not show stent patterning after annealing. In the braided stent of the Stinson patent, tube formation and stent pattern formation are the same step, *i.e.* braiding the tube over a mandrel. There is no teaching or suggestion of the process sequence as recited in claim 21. At least for this additional reason the anticipation rejection of claim 21 should be reversed.

B The Examiner Erred in Rejecting Claims 1–11, 15–24, and 26-32 under 35 U.S.C. § 103 over Healy et al US 5,670,161in View of Penny III et al, US

4,816,029.

1. **Claims 1–11, 15–24, 26-32 - Annealing an Expanded Tubular Article or Stent**

As initial matter it must be clarified what claims have been rejected under this combination. The statement of the rejection on page 3 of the 6/30/2008 Office Action lists claims 1–11, 15–24, 26 and 29. The Office Action does not mention claims 27-28 or 30-32. However, the Office Action Summary lists claims 27-28 and 30-32 as rejected; page 4 of the Office Action mentions claim 27-28 and 30-32 in the discussion of this rejection; and there is no other articulated ground for rejection of claims 27-28 or 30-32. Consequently the Healy/Penny obviousness rejection is treated as having been applied to claims 27-28 and 30-32 for purposes of this Appeal.

All of the independent claims recite an annealing step performed on an expanded diameter tubular article or stent to shrink its diameter to a reduced diameter. Neither Healy (Exhibit D) nor Penny (Exhibit E) teach such a step.

The Examiner contends:

> Healy discloses in fig 5, a process for forming a stent having the limitations of claims 1- 23, including: the process comprises the step of forming a tubular stent of the polymer material (see col 9, lines 22-46); the stent radially expanding to produce an expanded diameter stent (see col. 3, lines 9-45), and at least one time repeating of steps a-b are all performed prior to deployment of the stent in a body (see col., 7, lines 50-67), but Healy is silent regarding the step of annealing the expanded diameter stent or tubular article to shrink its diameter to a reduced diameter.
>
> Penny teaches annealing the expanded diameter stent to shrink its diameter to a reduced diameter (see col. 4, lines 42-57).

It is true that Healy fails to disclose annealing an expanded diameter stent or tubular article to shrink its diameter to a reduced diameter. It is *not true* that Healy otherwise discloses a process having the limitations of claims 1-23.

The stents of Healy (Exhibit D) are formed in the configuration for delivery (col. 8, line 66- col. 9, line 3). The stents may be formed in a number of ways (*see e.g.* col 8, lines 49-65 and col. 9 lines 17- 65). None involve annealing an expanded diameter stent or tube to shrink its diameter.

Healy's stents are heated at the time of expansion (*see* col. 3, lines 39-45 and col. 10. line 66 - col. 11, line 3, and col. 11, lines 32-51). The heating and expansion of the stents occurs when the stent is deployed in the body (col. 8, lines 5-7). The heating allows the polymer material to plastically deform so that it retains its expanded configuration when cooled (*see* col. 7, lines 50-61 where Healy teaches that following the heated expansion the stent is cooled and "remains open").

Annealing is mentioned at col. 10, lines 62-65 of Healy, but this disclosure pertains to annealing the stents as formed, not to annealing expanded diameter stents or tubular articles. Furthermore, there is no indication that the stent diameter is shrunk when annealed. Annealing can be done on a mandrel, so diameter shrinking is clearly not necessarily inherent in Healy's context. In the 6/30/2008 Action the Examiner acknowledges that "Healy is silent regarding the step of annealing the expanded diameter stent or tubular article to shrink its diameter to a reduced diameter."

Regarding the combination of Healy with Penny, the Examiner is, once again, clearly wrong in asserting that "Penny teaches annealing the expanded diameter stent to shrink its diameter to a reduced diameter …".

Penny describes a polymer heart valve stent (Exhibit E). There is no teaching that this stent *ever* undergoes expansion, much less that it does so before the annealing step. The cited passage of Penny pertaining to annealing (*i.e.* col. 4, lines 42-57) is as follows.

> The stents of the present invention are preferably injection-molded of polypropylene or other suitable biocompatible thermoplastic polymeric material. Polypropylene is particularly preferred because it is readily molded, has good strength, and has a moderate degree of flexibility which is desirable to relieve stresses on the stent and the valve material during use. Other suitable materials include Delrin polymer (a polyformaldehyde of greater than 15,000 molecular weight sold by DuPont), Lexan polymer (a polycarbonate), nylon (a hexamethylene diamine-adipic acid polymer) and high density polyethylene. The molded stents are desirably annealed to relieve internal stress and subsequently polished and inspected before covering with cloth. Polypropylene stents may be suitably annealed by heating in an oven at about 90° C. for 20 minutes.

This describes annealing a stent that has been formed by injection molding. No reasonable argument can be made that an injection molded stent as formed is an "expanded diameter" stent or tube within the meaning of any of the claims at issue in this rejection.

There is nothing whatsoever in Penny that pertains to an "expanded diameter stent" much less annealing such a stent. Further, nothing is said about shrinkage and the passage cited by the Examiner does not clearly exclude a mandrel so shrinkage cannot be properly inferred to be inherent. Penny adds nothing of relevance to Healy.

The combination of Healy and Penny therefore, does not meet the recitations of any of the rejected claims.

At least for this reason, all of the rejected claims are seen to be both novel and non-obvious over the cited documents. Reversal of the rejection of 1-11, 15-24 and 26-32 for obviousness from Healy in view of Penny is respectfully requested.

2. Additional Argument for Claims 1 – 11, and 15 – 24 - Prior to Deployment in the Body

According to independent claims 1, 15, 17 and 21 the recited steps are "all performed prior to deployment in the body."

The 6/30/2008 Office Action contends that Healy discloses radially expanding a stent prior to deployment in the body. This is clearly wrong. Healy's stents are not radially expanded ***prior to stent delivery***.

The Examiner cites col. 7, lines 50-67 for the assertion that Healy teaches expansion prior to delivery. The full text of this paragraph, which continues to col. 8, line 4, is reproduced below.

> Using the heating techniques described more fully below, the temperature of the polymer can be increased incrementally to a point near the glass-transition temperature of the copolymer, permitting the stent to enter a rubbery phase that takes advantage of a lower elastic modulus. In this phase, the stent may be plastically deformed and the shape stabilized prior to any viscoelastic behavior (such as creep, stress relaxation, strain recovery, or shrinkage) causes the stent to return to its unexpanded shape or to diminish in strength. ***Following expansion,*** the polymer is allowed to cool, but because plastic deformation has occurred, ***the stent remains open***. Attempting to expand the stent of the present invention below the glass-transition temperature causes the stent to fracture as a result of its brittle or glassy characteristics below the glass-transition temperature. This could be potentially hazardous, depending upon whether and how the stent fractures as a result of being expanded improperly. Thus, controlled heating and expansion of the stent is important to the invention, as it results in a circumferential drawing of the extruded stent, helping to orient the copolymer molecules, and thereby enhances the modulus and strength of the materials, and ultimately the strength of the stent.
>
> (emphasis added)

The Examiner has clearly misrepresented the paragraph. Nothing in this paragraph indicates that it is speaking of the stent prior to deployment. To the contrary, the "remains open" teaching would prevent delivery of the Healy stent if it occurred prior to the time the stent is deployed.

Furthermore the Examiner has ignored the critical context statement which is found in the first sentence of the next paragraph:

> ***The thermo-mechanical expansion of the stent*** is considered a processing step ***occurring in situ and concomitant with deployment.***
>
> (col. 8, lines 5-7, emphasis added)

That is, the thermo-expansion step described at col. 7, lines 50 - col. 8 line 4, is expressly taught as one that is performed in body at the time of deployment, not prior to deployment as recited in claims 1–11 and 15–24. Thus the only description in Healy of expanding the stents to an expanded diameter is in the context of expansion at the site of deployment, and the skilled person has no motivation to expand prior to deployment because the stent "remains open" after expansion.

At least for the additional reasons given above reversal of the rejection of 1-11 and 15-24, for obviousness from Healy in view of Penny is respectfully requested.

3. Claims 2, 15-16, 18, 22, 29 - Repetition of expansion and annealing/shrinking steps

Claims 2, 15-16, 18, 22, and 19 recite repetition of the radial expansion and annealing/shrinking steps at least once. The repetition is performed on the ***same*** antecedent article and, as such, is not met merely by performing the same steps once on a plurality of different stents or tubes.

The Examiner has cited Healy col. 7, lines col. 7, lines 50-67 as showing repetition of "steps a–b." The applicant has repeatedly pointed out that repetition of a step a) is not recited in any claim. Repetition of steps a-b, even if it were taught by Healy,[1] does not meet the recitation of these claims.

There is no teaching in Healy that can be reasonably construed as suggesting repetitive expansion and shrinking of the same stent or tube. The same is true for Penny. No reasonable argument can be made that a skilled person would be motivated by any teaching in

[1] It isn't, see the extended quotation above.

these documents to repetitively expand and anneal either of these stents.

Still further, the application (page 9, lines 22-25) teaches that multiple expansions and annealings performed on the same tubular article can provide cumulatively increased radial orientation of the polymer material. This is a novel and non-obvious benefit not hinted at by anything in Healy or in Penny.

At least for these additional reasons reversal of the obviousness rejection of claims 2, 15-16, 18, 22, and 19 from Healy in view of Penny is respectfully requested.

4. Claims 8, 9 and 31 - Radial Expansion below Glass Transition Temperature

Claims 8 and 31 recite that the radial expansion step is performed at a temperature below the glass transition temperature of the polymer material. Claim 9 depends from claim 8.

The above quoted portion of the Healy patent (col. 7, line 50- col. 8, line 4) clearly and unambiguously teaches that the stent is to reach "a rubbery phase," at the time of expansion. This is the characteristic of polymer material at or above its glass transition temperature. Healy also teaches that "[a]ttempting to expand the stent of the present invention below the glass-transition temperature ***causes the stent to fracture*** as a result of its brittle or glassy characteristics below the glass-transition temperature" (emphasis added). No one would want this consequence. Consequently Healy clearly is ***teaching away*** from radially expanding the stent below the glass-transition temperature. Taken together these statements clearly teach the skilled person that Healy's "near the glass-transition temperature" only pertains to temperatures that are actually *at or above* the glass transition temperature of the material. Healy's expansion step therefore does not meet the recitations of claims 8, 9 or 31.

At least for this additional reason reversal of the obviousness rejection of claims 8, 9 and 31 from Healy in view of Tower is respectfully requested.

5. Claim 9 - Radial Expansion at Room Temperature

Claim 9 depends from claim 8 and further specifies the temperature of the radial expansion step as room temperature. This cannot reasonably be argued to be near the glass transition temperature for any of Healy's stent materials. At least for this additional reason reversal of the obviousness rejection of claim 9 Healy in view of Tower is respectfully requested.

IV. Conclusion

For at least the reasons presented above, claims 1 – 11, 15 – 24, and 26 – 32 are non-obvious over the cited art. Consequently, reversal of the rejections is respectfully requested.

Respectfully submitted,
VIDAS, ARRETT & STEINKRAUS

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(viii) Claims Appendix

Claim 1. A process comprising the steps of:

a) forming a generally tubular stent of polymer material;

b) radially expanding the stent to produce an expanded diameter stent; and then,

c) annealing the expanded diameter stent to shrink its diameter to a reduced diameter,

wherein the steps a) - c) are all performed prior to deployment of the stent in a body.

Claim 2. A process as in claim 1 further comprising at least one time repeating steps b) and c) in sequence on said stent.

Claim 3. A process as in claim 1 wherein in step a) the stent is formed by molding the polymer material.

Claim 4. A process as in claim 3 wherein the polymer material is thermoplastic.

Claim 5. A process as in claim 4 wherein the polymer material is biodegradable.

Claim 6. A process as in claim 1 wherein the polymer material is selected from the group consisting of poly(alpha-hydroxy acid), polylactic acid-polyethylene oxide copolymers; modified cellulose; collagen or other connective proteins; adhesive proteins; hyaluronic acid; polyanhydrides; polyphosphoesters; poly(amino acids); copolymers thereof; and mixtures of any of said materials.

Claim 7. A process as in claim 6 wherein the polymer material is a poly(alpha-hydroxy acid) selected from the group consisting of homopolymers and copolymers of polylactide (PLA), poly-L-lactide (PLLA), poly-D-lactide (PDLA), polyglycolide (PGA), polydioxanone, polycaprolactone, poly(hydroxybutyrate), polygluconate, and mixtures thereof.

Claim 8. A process as in claim 1 wherein the step b) is performed at a temperature below the glass transition temperature of the polymer material.

Claim 9. A process as in claim 8 wherein the step b) is performed at room temperature.

Claim 10. A process as in claim 1 wherein the step c) is performed at a temperature above the glass transition temperature of the polymer material.

Claim 11. A process as in claim 10 wherein the step c) is performed at a temperature within the range of about 90°C to about 150°C.

Claim 15. A process comprising the steps of:

a) forming a generally tubular article of polymeric material;

b) radially expanding the article to produce an expanded diameter article; and then,

c) annealing the expanded diameter article to shrink its diameter to a reduced diameter,

wherein the steps a) - c) are all performed prior to deployment of the tubular article in a body, and wherein at least one time steps b) and c) are repeated in sequence on said tubular article.

Claim 16. A medical device adapted for body lumen navigation and/or treatment produced by the process of claim 15.

Claim 17. A process comprising the steps of:

a) forming a generally tubular article of polymeric material;

b) radially expanding the article to produce an expanded diameter article; and then,

c) annealing the expanded diameter article to shrink its diameter to a reduced diameter,

wherein the steps a) - c) are all performed prior to deployment of the tubular article in a body, and wherein the polymer material is a biodegradable polymer.

Claim 18. A process as in claim 17 wherein at least one time steps b) and c) are repeated in sequence on said tubular article.

Claim 19. A process as in claim 17 wherein the polymer material is selected from the group consisting of poly(alpha-hydroxy acid), polylactic acid-polyethylene oxide copolymers; modified cellulose; collagen or other connective proteins; adhesive proteins; hyaluronic acid; polyanhydrides; polyphosphoesters; poly(amino acids); copolymers thereof; and mixtures of any of said materials.

Claim 20. A medical device adapted for body lumen navigation and/or treatment produced by the process of claim 17.

Claim 21. A process comprising the steps of:

a) forming a tube of polymeric material;

b) radially expanding the tube to produce an expanded diameter tube;

c) annealing the expanded diameter tube to shrink its diameter to a reduced diameter; and subsequently

d) forming a stent from the annealed tube,

wherein the steps a) - d) are all performed prior to deployment of the stent in a body.

Claim 22. A process as in claim 21 wherein the steps b) and c) are repeated at least once on said tube before step d) is performed.

Claim 23. A process as in claim 21 wherein in step d) the stent is formed by machining or etching the reduced diameter tube obtained from step c).

Claim 24. A process as in claim 1 wherein in step a) a pattern of perforations is provided in the tube wall.

Claim 26. A process comprising the steps of:

a) forming a generally tubular article;

b) radially expanding the tubular article to produce an expanded diameter tubular article; and

c) annealing the expanded diameter tubular article to shrink its diameter to a reduced diameter,

the process further comprising

d) forming the tubular article as a stent with a pattern of perforations therein.

Claim 27. A process as in claim 26 wherein the tubular article formed with said pattern of perforations before said radially expanding step b).

Claim 28. A process as in claim 26 wherein the tubular article formed with said pattern of perforations after said annealing step c).

Claim 29. A process as in claim 26 further comprising at least one time repeating steps b) and c) on said tubular article.

Claim 30. A process as in claim 26 wherein the tubular article is formed of thermoplastic polymer material.

Claim 31. A process as in claim 30 wherein the step b) is performed at a temperature below the glass transition temperature of the polymer material.

Claim 32. A process as in claim 26 wherein the tubular article is made of biodegradable polymer material.

(ix) Evidence Appendix

A Stinson, US 6,719,934

B. Stinson, US 6,245,103

C. "First Appeal" Appeal Brief filed 2/16/2005

D. Healy et al US 5,670,161

E. Penny III et al, US 4,816,029

F. 3/3/2006 Requirement for Restriction/Election

(x) Related Proceedings Appendix

NA.

(12) **United States Patent**
Stinson

(10) **Patent No.: US 6,719,934 B2**
(45) **Date of Patent: Apr. 13, 2004**

(54) **PROCESS FOR MAKING BIOABSORBABLE SELF-EXPANDING STENT**

(75) Inventor: **Jonathan S. Stinson**, Plymouth, MN (US)

(73) Assignee: **Boston Scientific Scimed, Inc.**, Maple Grove, MN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 284 days.

(21) Appl. No.: **09/843,425**

(22) Filed: **Apr. 25, 2001**

(65) **Prior Publication Data**

US 2001/0021871 A1 Sep. 13, 2001

Related U.S. Application Data

(62) Division of application No. 08/904,467, filed on Aug. 1, 1997, now Pat. No. 6,245,103.

(51) **Int. Cl.**[7] **D02G 3/44**; D02J 13/00; D04C 1/06

(52) **U.S. Cl.** **264/40.1**; 87/9; 264/103; 264/235

(58) **Field of Search** 264/40.1, 103, 264/235; 87/9

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,697,969 A * 12/1997 Schmitt et al. 623/1.44

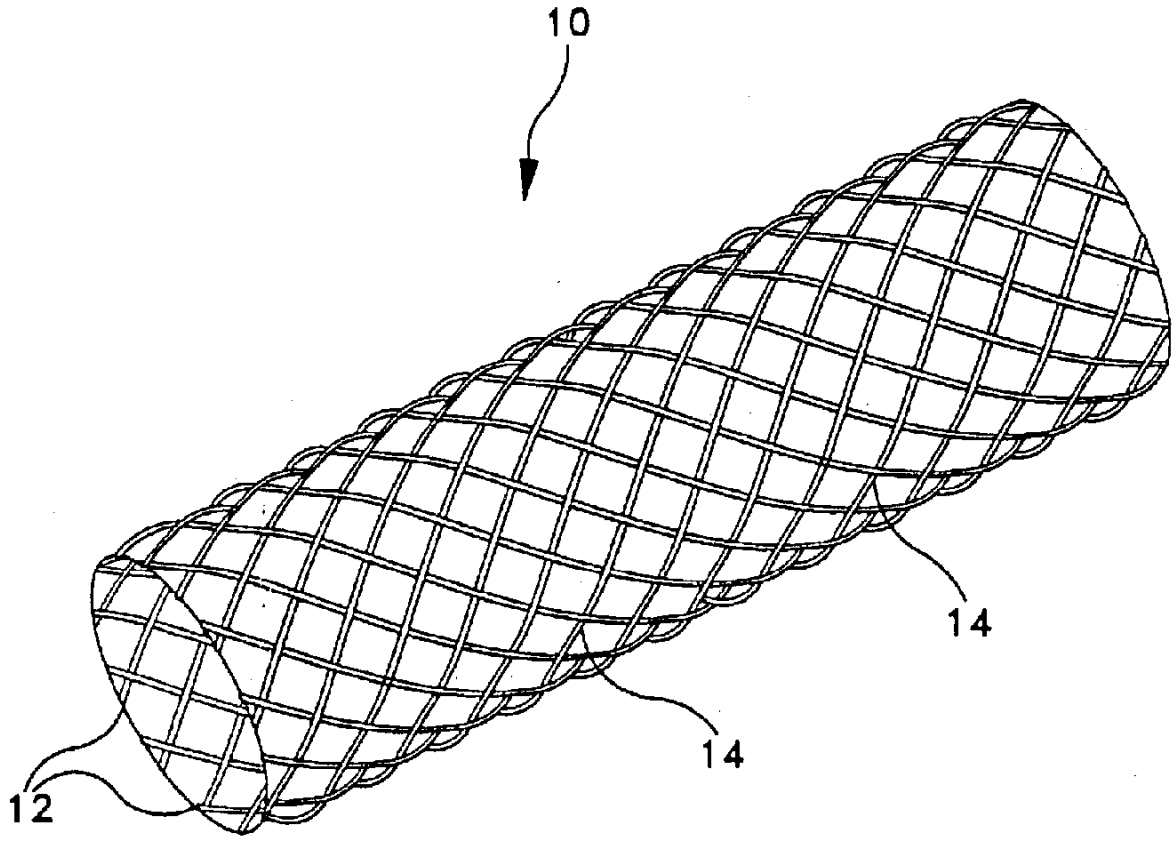
* cited by examiner

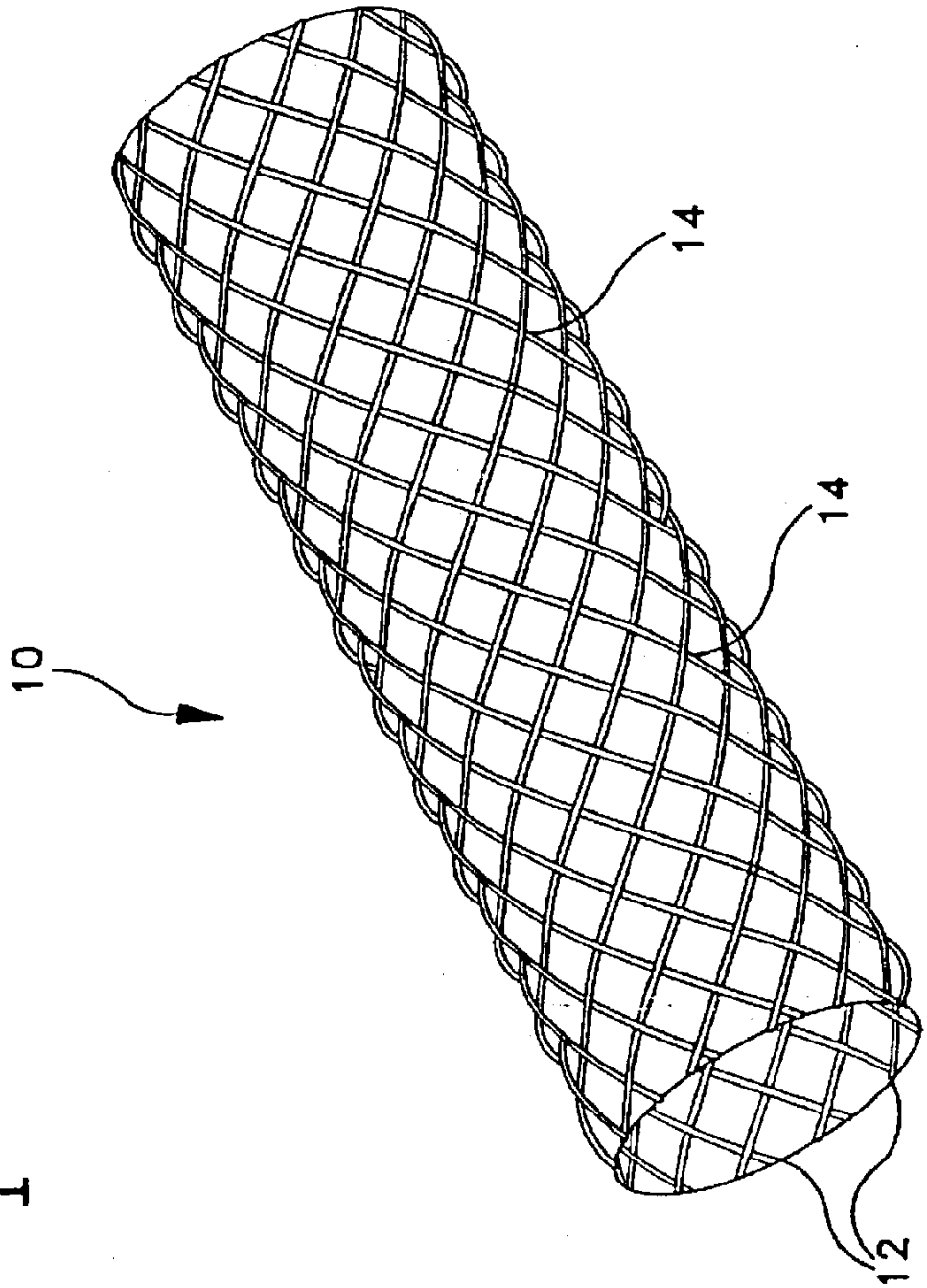
Primary Examiner—Leo B. Tentoni
(74) *Attorney, Agent, or Firm*—Larkin Hoffman Daly & Lindgren Ltd.; Frederick W. Niebuhr, Esq.

(57) **ABSTRACT**

A self-expanding stent formed from helically wound and braided filaments of bioabsorbable polymers such as PLA, PLLA, PDLA, and PGA.

27 Claims, 16 Drawing Sheets





FIG—1

FIG-2

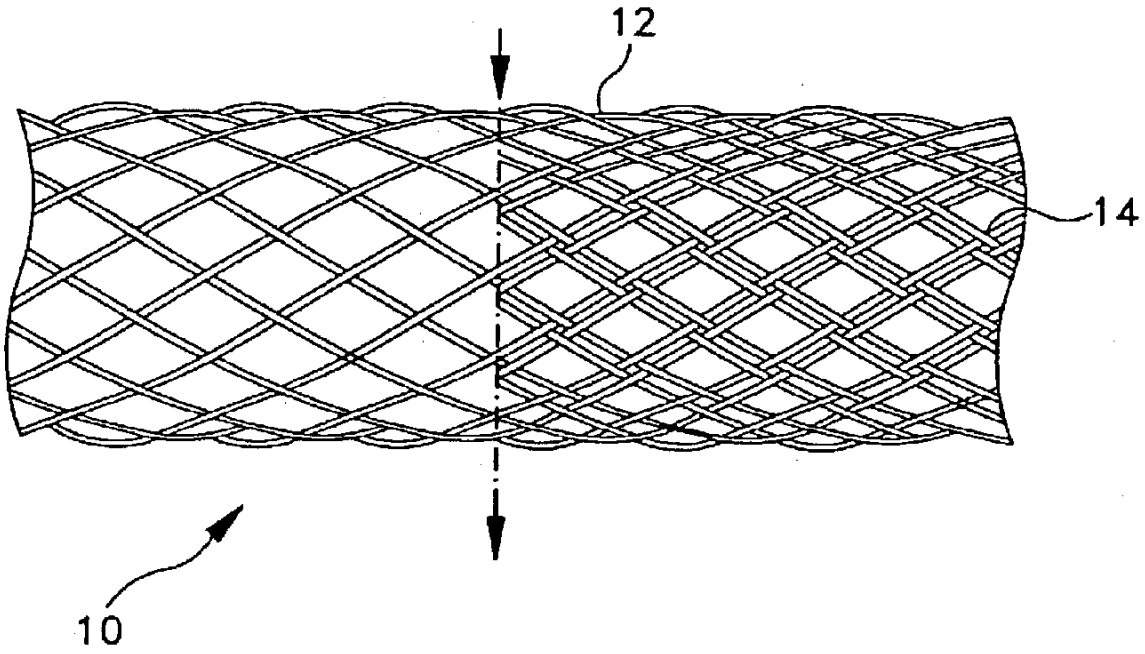
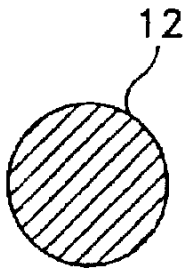


FIG-3



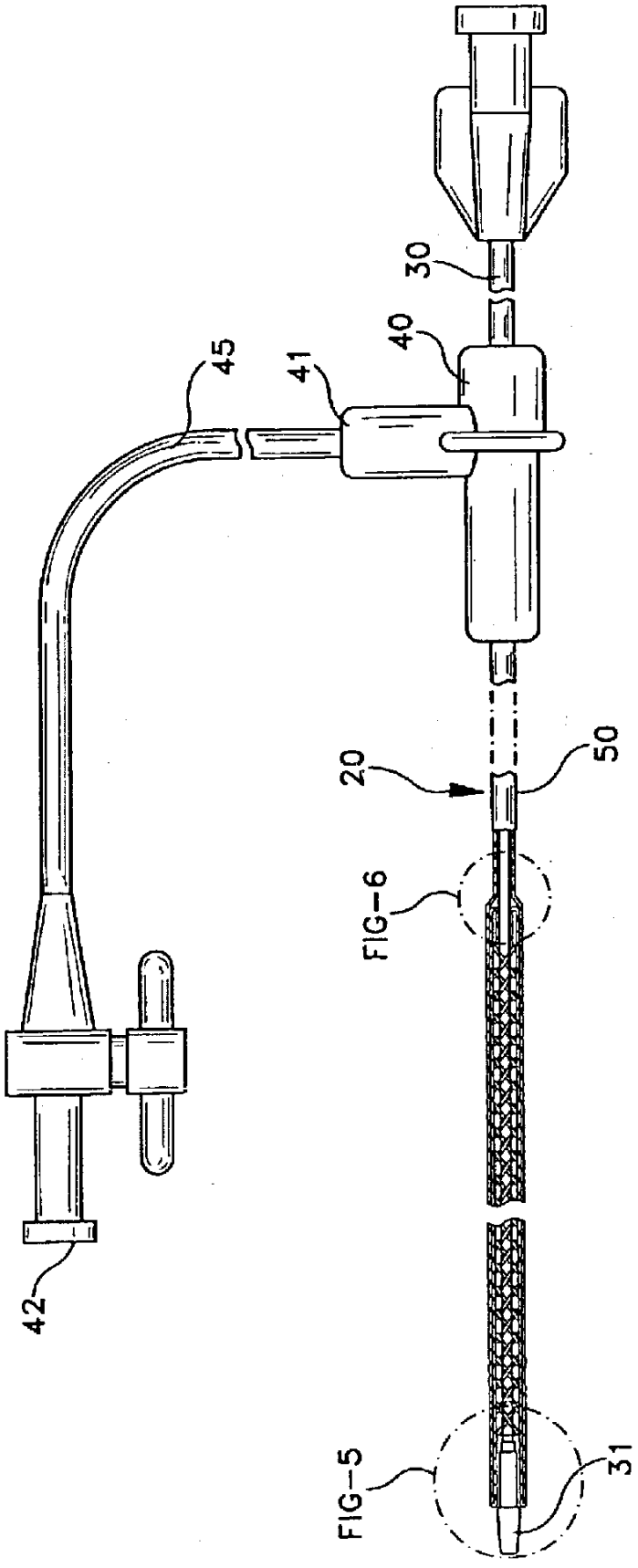


FIG-4

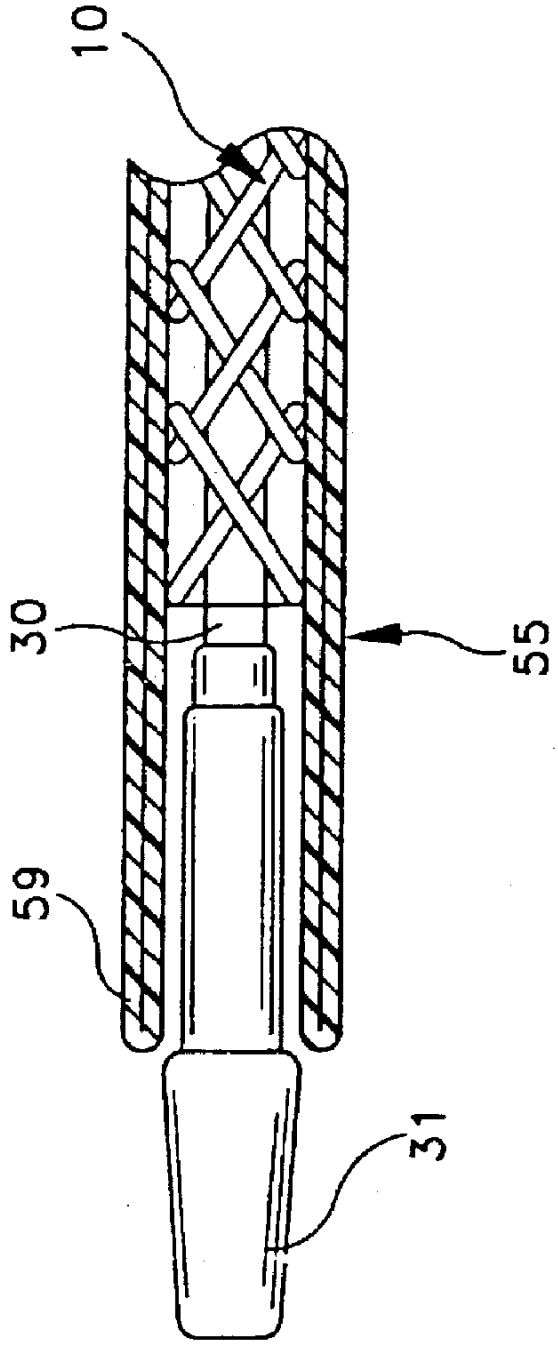


FIG-5

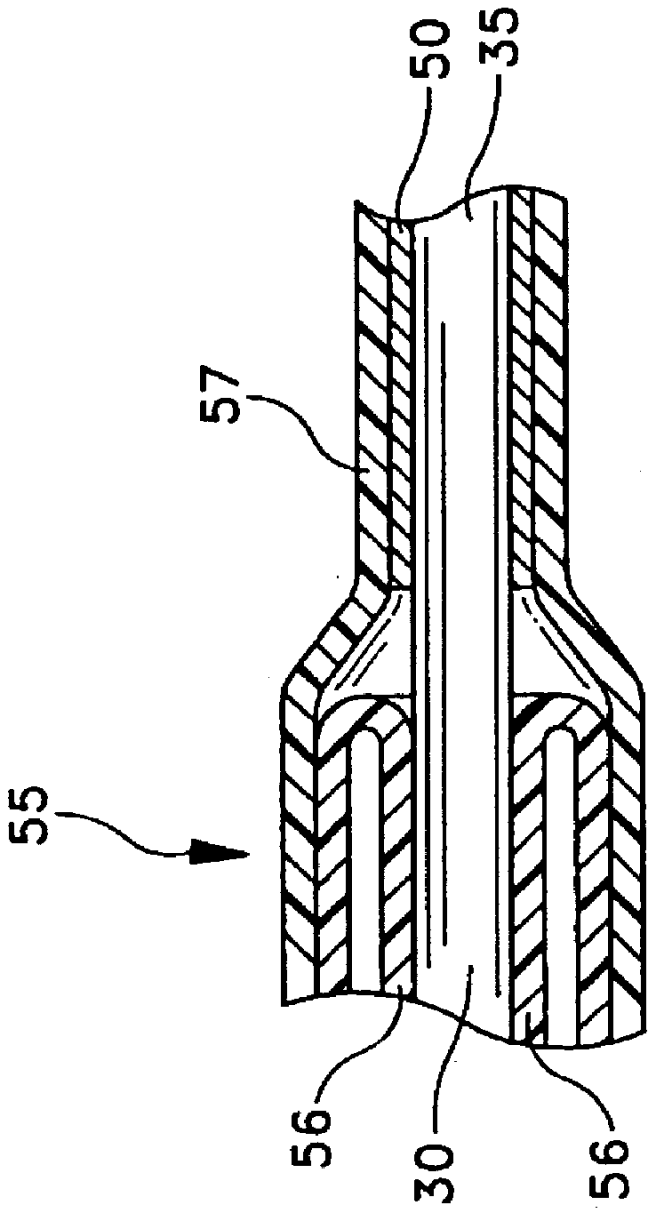
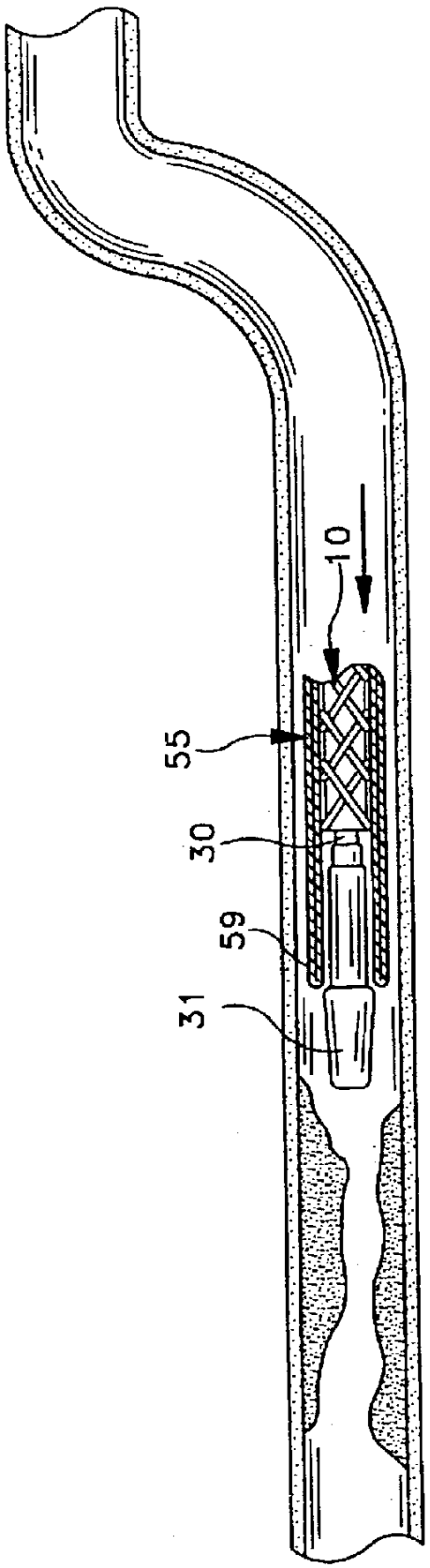
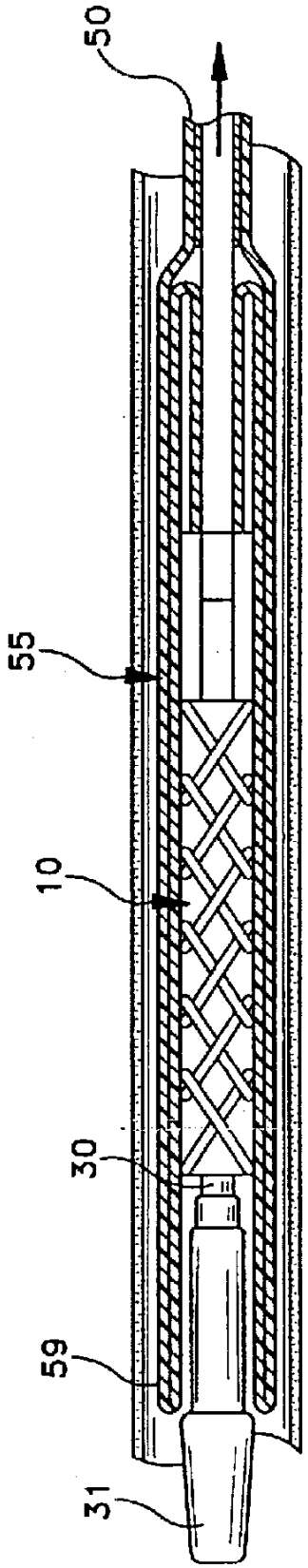


FIG-6



FIG—7



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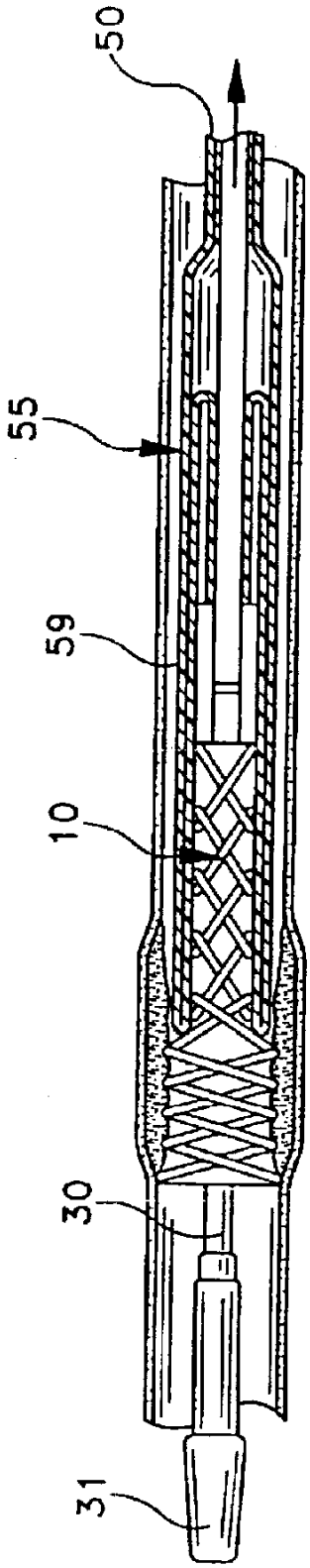


FIG-9

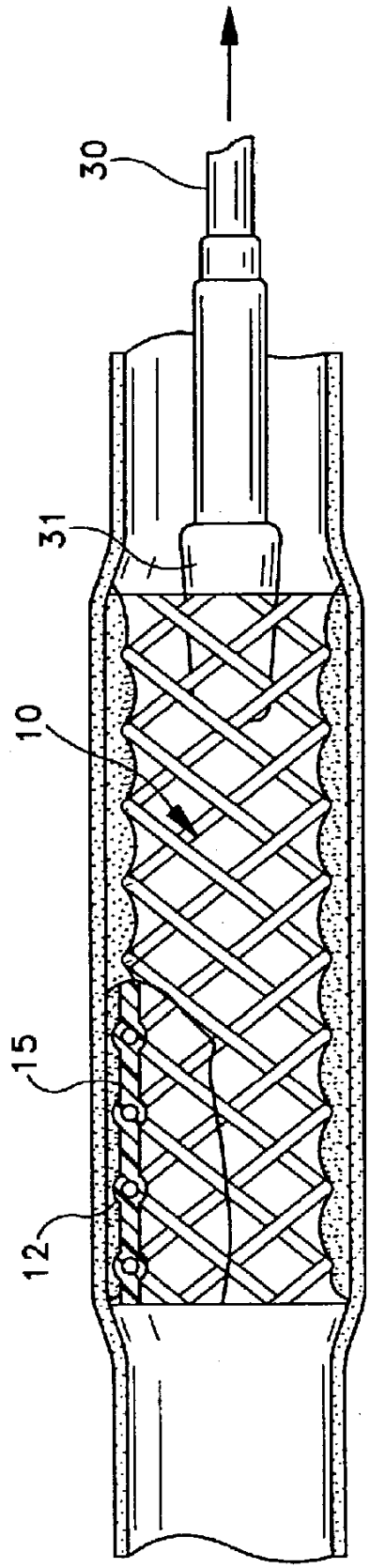


FIG-10

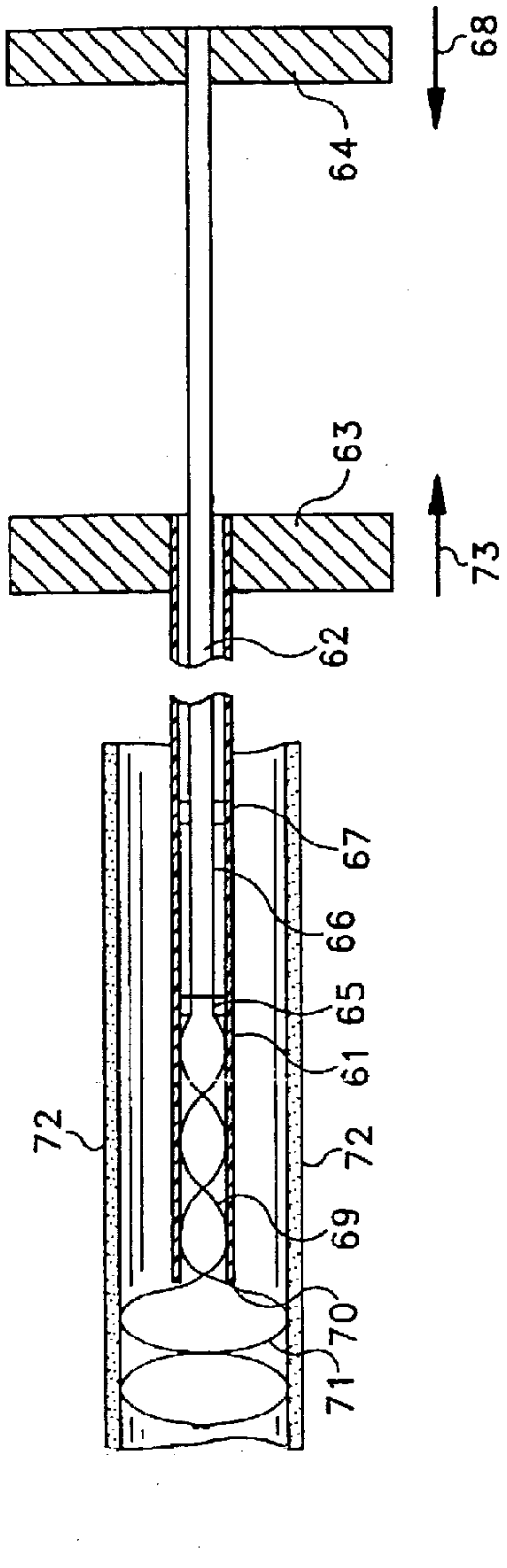


FIG-11

FIG-12

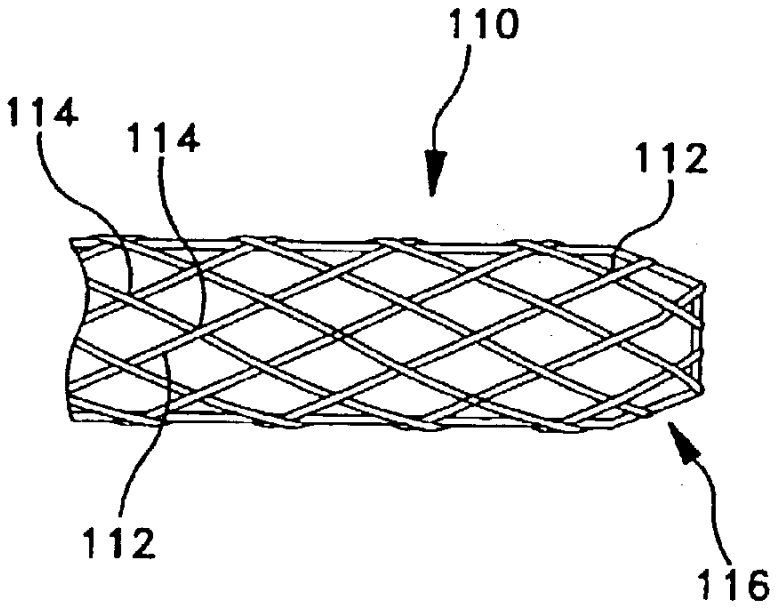


FIG-13

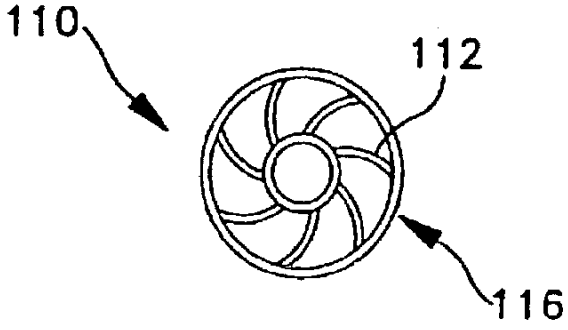
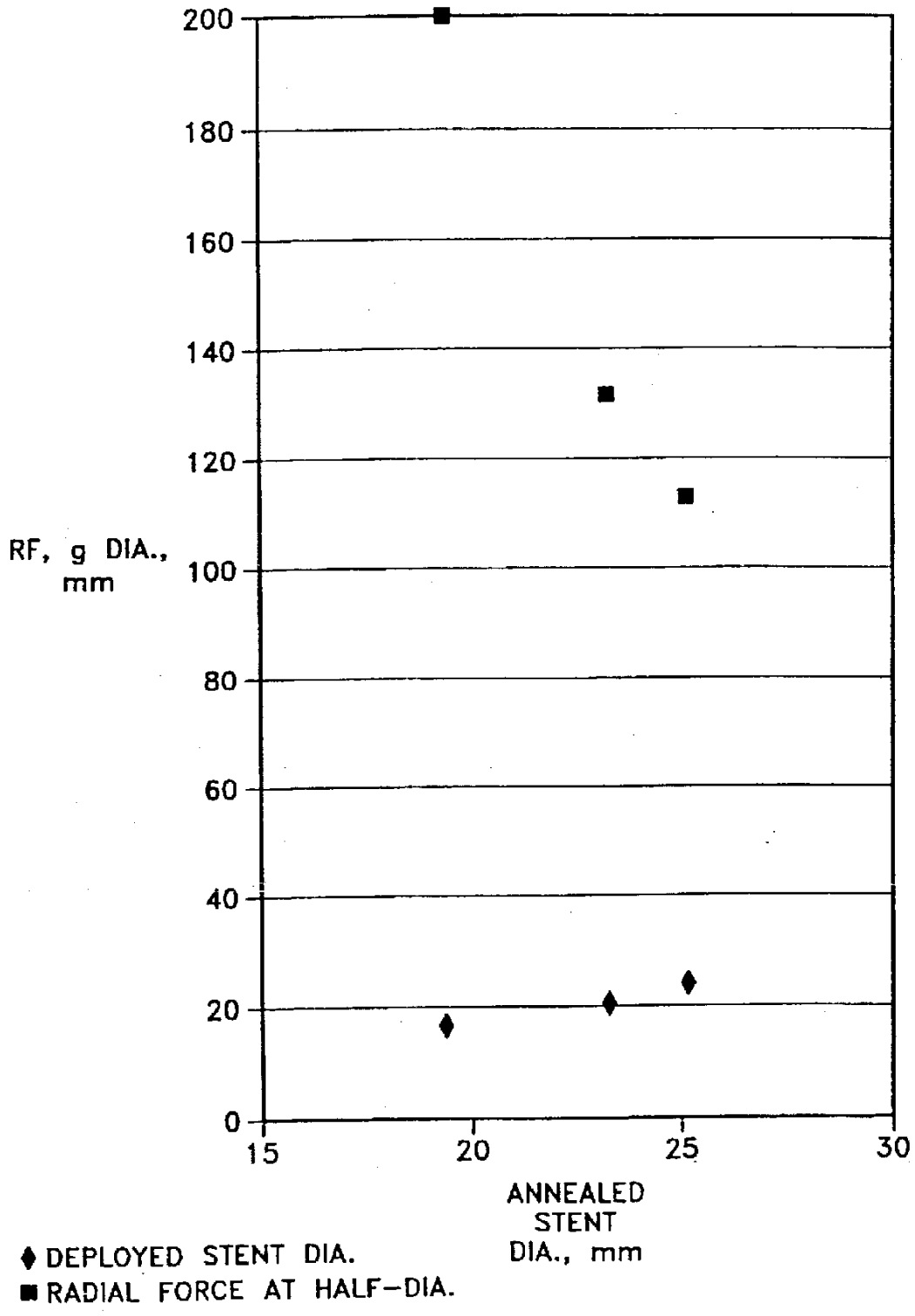


FIG-14


200
180
160
140
120
100
80
60
40
20
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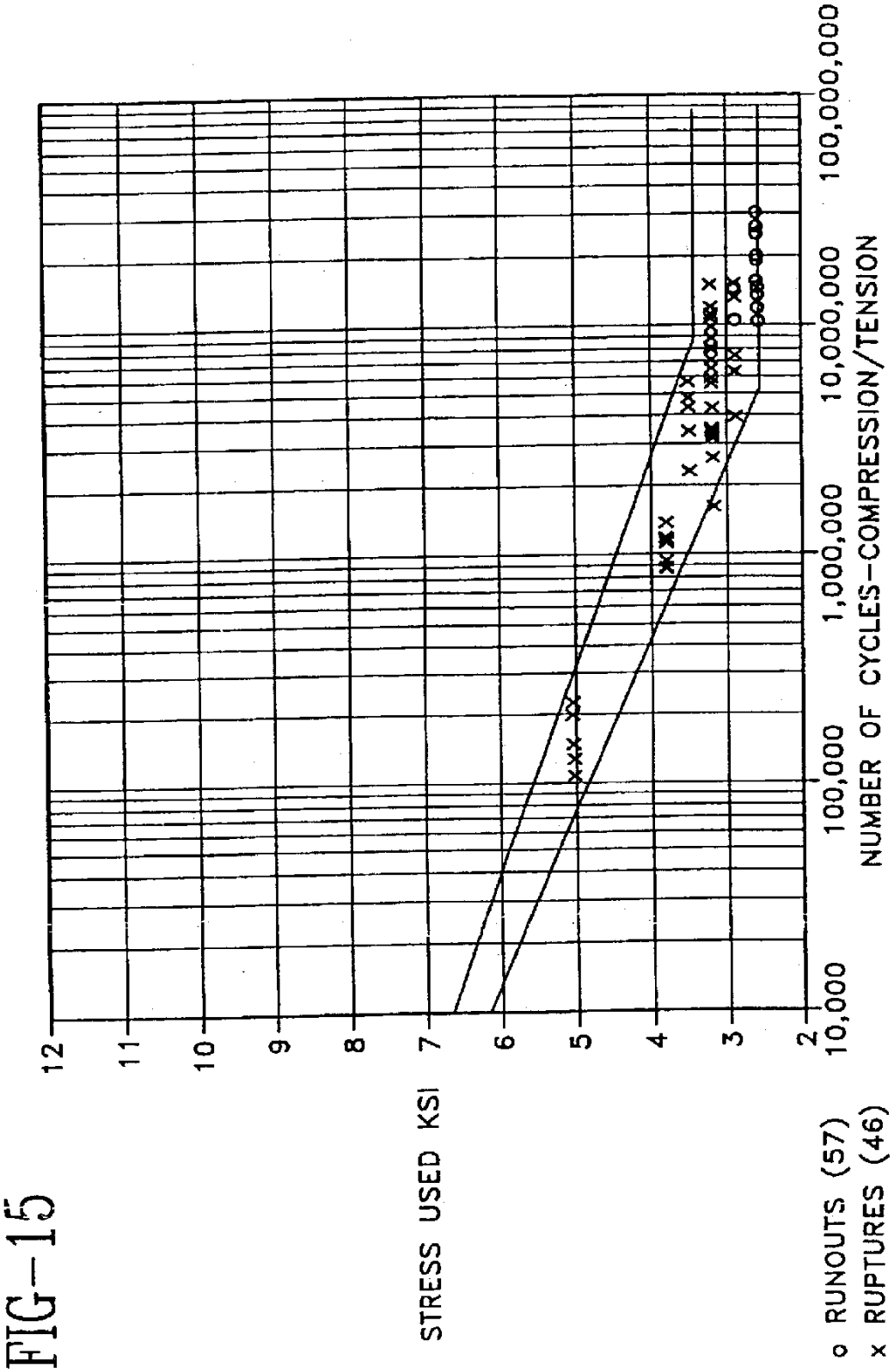
RF, g DIA., mm
15
20
25
30
ANNEALED STENT DIA., mm
♦ DEPLOYED STENT DIA.
■ RADIAL FORCE AT HALF-DIA.


STRESS USED KSI
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11
10
9
8
7
6
5
4
3
2
10,000
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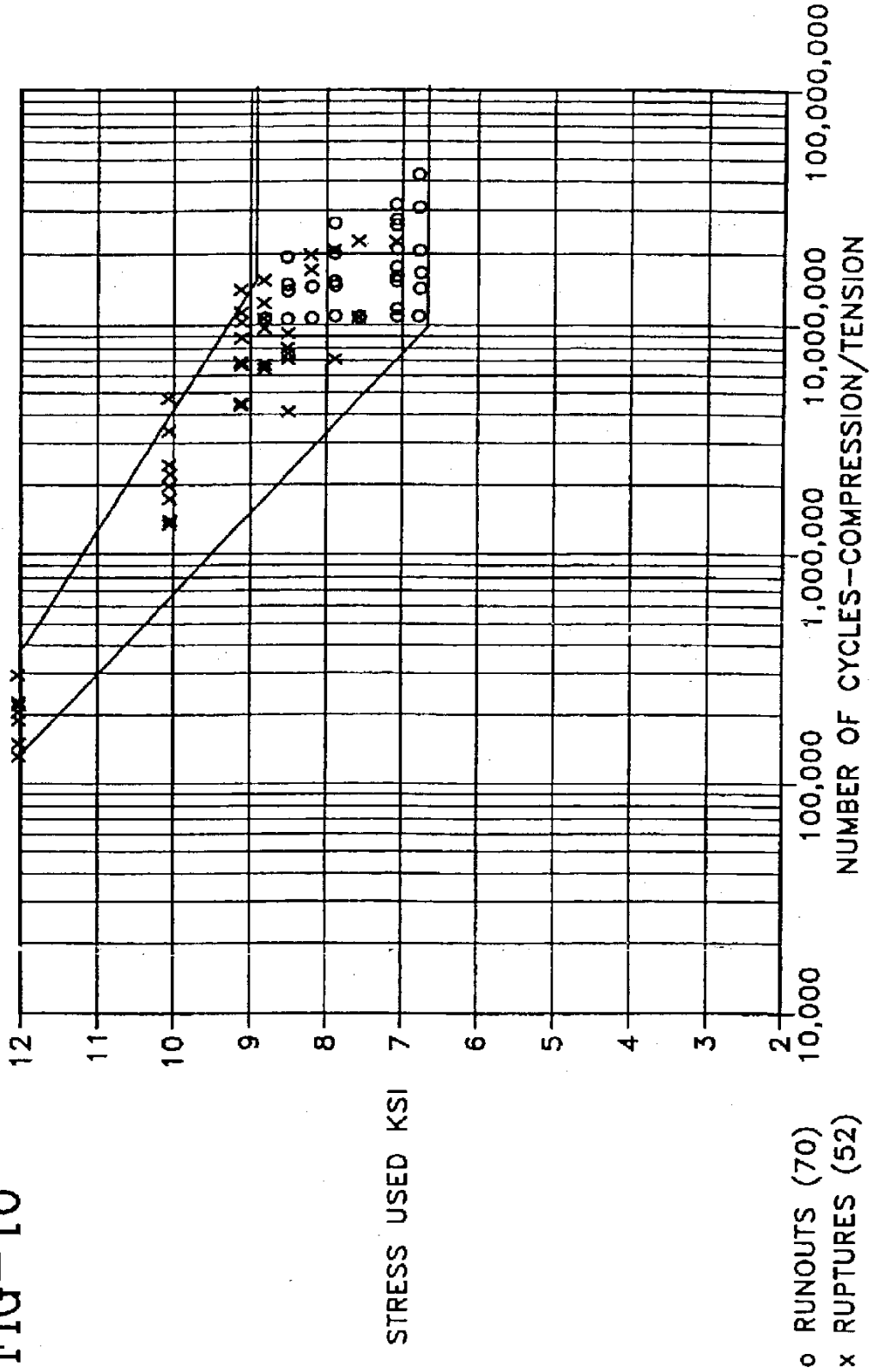
NUMBER OF CYCLES-COMPRESSION/TENSION
o RUNOUTS (57)
x RUPTURES (46)

FIG-15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NUMBER OF CYCLES-COMPRESSION/TENSION
STRESS USED KSI
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x RUPTURES (52)

FIG-16

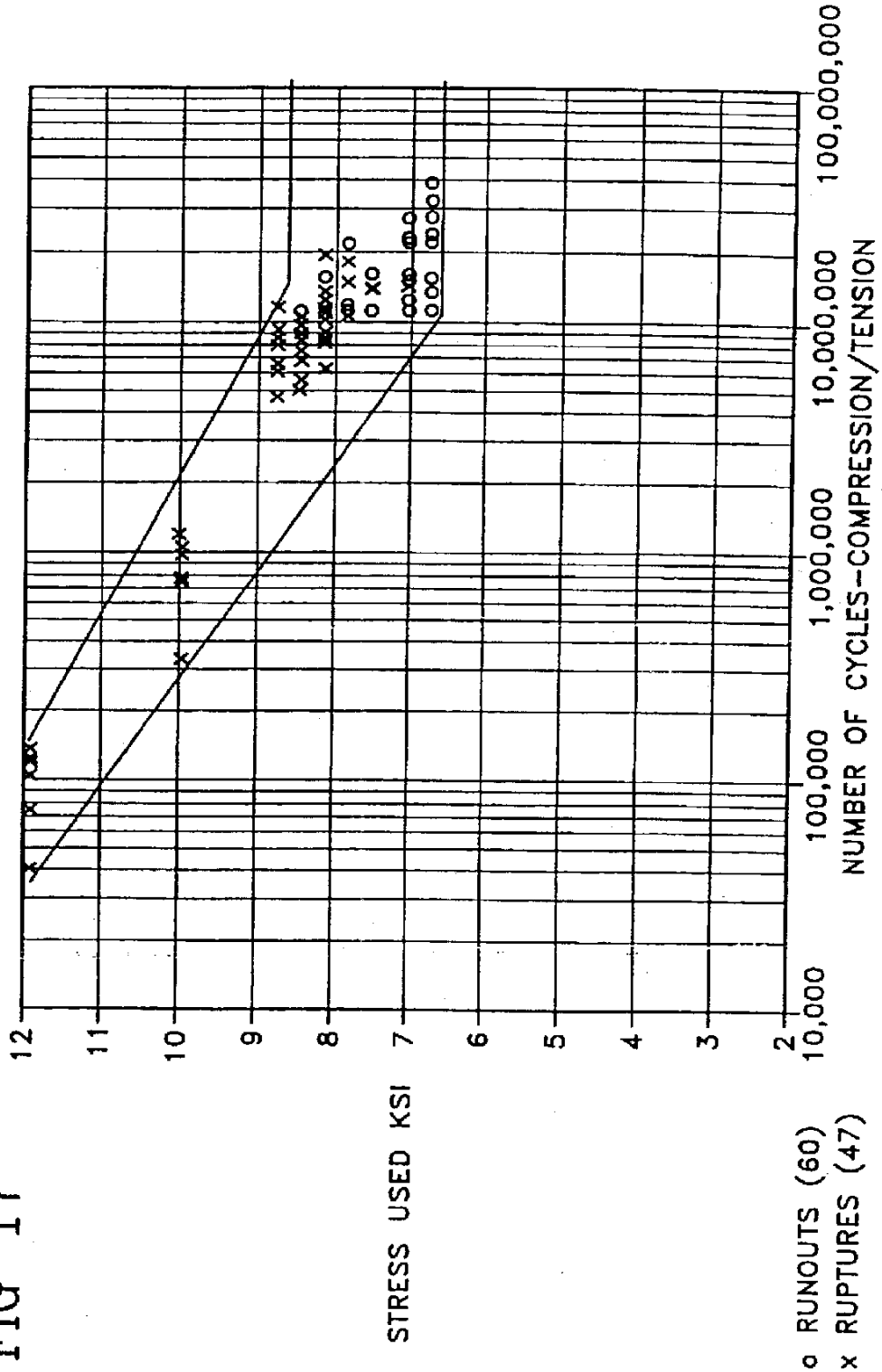
STRESS USED KSI
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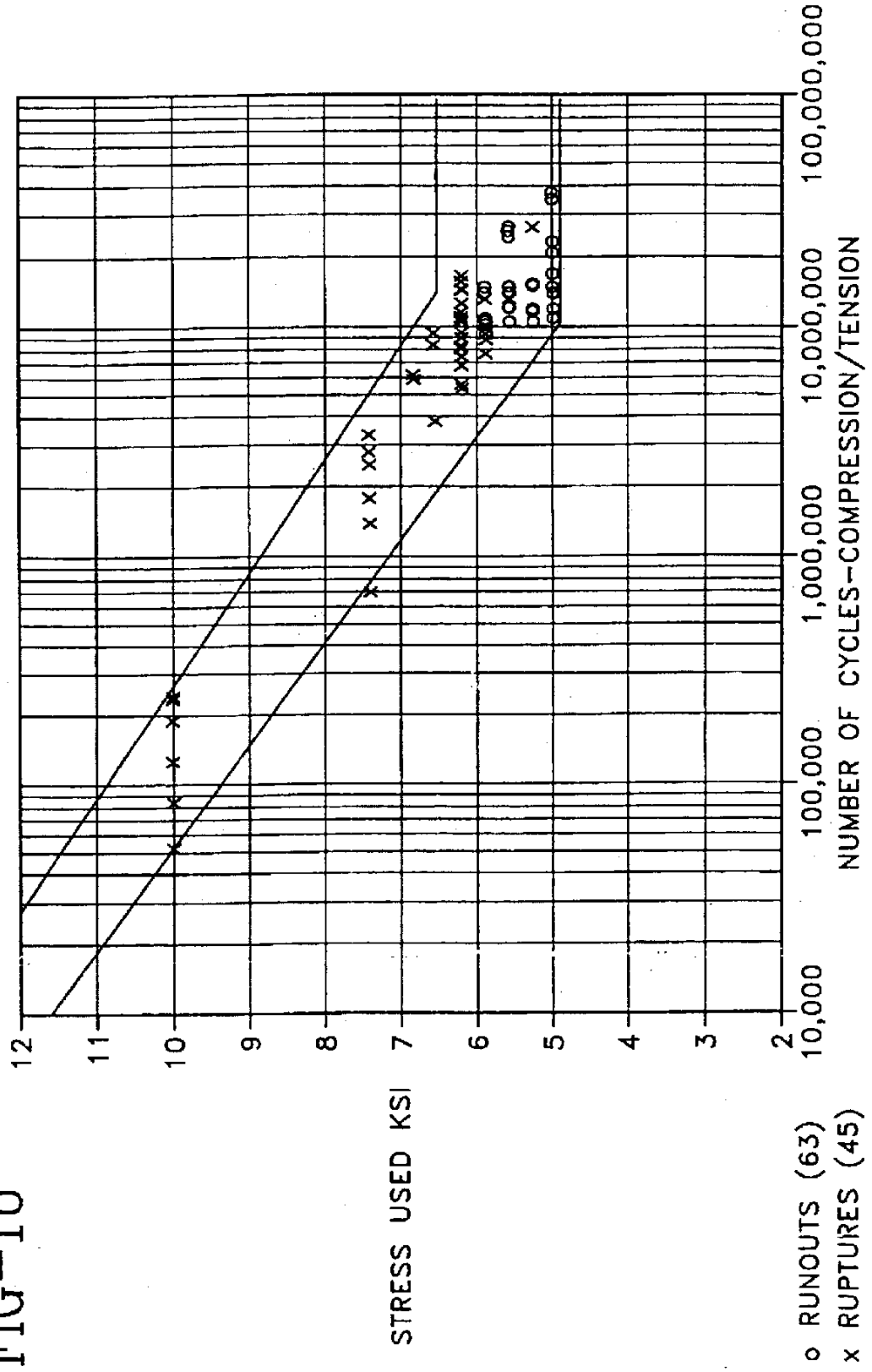
FIG-17


STRESS USED KSI
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100,000,000
NUMBER OF CYCLES-COMPRESSION/TENSION
o RUNOUTS (63)
x RUPTURES (45)

FIG-18

PROCESS FOR MAKING BIOABSORBABLE SELF-EXPANDING STENT

This is a divisional of application Ser. No. 08/904,467 entitled "Bioabsorable Self-Expanding Stent," filed Aug. 1, 1997 now U.S. Pat. No. 6,245,103.

BACKGROUND OF THE INVENTION

The present invention relates generally to implantable, radially expandable medical prostheses which are frequently referred to as stents. In particular, the present invention is a bioabsorbable self-expanding stent.

Self-expanding medical prostheses frequently referred to as stents are well known and commercially available. They are, for example, disclosed generally in the Wallsten U.S. Pat. No. 4,655,7.1, the Wallsten et al. U.S. Pat. No. 5,061, 275 and in Hachtmann et al., U.S. Pat. No. 5,645,559. Devices are used within body vessels of humans for a variety of medical applications. Examples include intravascular stents for treating stenoses, stents for maintaining openings in the urinary, biliary, tracheobronchial, esophageal, and renal tracts, and vena cava filters.

A delivery device which retains the stent in its compressed state is used to deliver the stent to a treatment site through vessels in the body. The flexible nature and reduced radius of the compressed stent enables it to be delivered through relatively small and curved vessels. In percutaneous transluminal angioplasty, an implantable endoprosthesis is introduced through a small percutaneous puncture site, airway, or port and is passed through various body vessels to the treatment site. After the stent is positioned at the treatment site, the delivery device is actuated to release the stent, thereby allowing the stent to self-expand within the body vessel. The delivery device is then detached from the stent and removed from the patient. The stent remains in the vessel at the treatment site as an implant.

Stents must exhibit a relatively high degree of biocompatibility since they are implanted in the body. An endoprosthesis may be delivered into a body lumen on or within a surgical delivery system such as delivery devices shown in U.S. Pat. Nos. 4,954,126 and 5,026,377. Preferred delivery devices for the present invention include U.S. Pat. Nos. 4,954,126; 5,026,377. Suitable materials for use with such delivery devices are described in U.S. patent application Ser. No. 08/833,639, filed Apr. 8, 1997.

Commonly used materials for known stent filaments include Elgiloy® and Phynox® metal spring alloys. Other metallic materials than can be used for self-expanding stent filaments are 316 stainless steel, MP35N alloy, and superelastic Nitinol nickel-titanium. Another self-expanding stent, available from Schneider (USA) Inc. of Minneapolis, Minn., has a radiopaque clad composite structure such as shown in U.S. Pat. No. 5,630,840 to Mayer. Self-expanding stents can be made of a Titanium Alloy as described in U.S. patent application Ser. No. 08/598,751, filed Feb. 8, 1996.

The strength and modulus of elasticity of the filaments forming the stents are also important characteristics. Elgiloy®, Phynox®, MP35N and stainless steel are all high strength and high modulus metals. Nitinol has relatively low strength and modulus.

The implantation of an intraluminal stent will preferably cause a generally reduced amount of acute and chronic trauma to the luminal wall while performing its function. A stent that applies a gentle radial force against the wall and that is compliant and flexible with lumen movements is preferred for use in diseased, weakened, or brittle lumens.

The stent will preferably be capable of withstanding radially occlusive pressure from tumors, plaque, and luminal recoil and remodeling.

There remains a continuing need for self-expanding stents with particular characteristics for use in various medical indications. Stents are needed for implantation in an ever growing list of vessels in the body. Different physiological environments are encountered and it is recognized that there is no universally acceptable set of stent characteristics.

A need exists for a stent which has self expanding characteristics, but which is bioabsorbable. A surgical implant such as a stent endoprosthesis must be made of a non-toxic, biocompatible material in order to minimize the foreign-body response of the host tissue. The implant must also have sufficient structural strength, biostability, size, and durability to withstand the conditions and confinement in a body lumen.

All documents cited herein, including the foregoing, are incorporated herein by reference in their entireties for all purposes.

SUMMARY OF THE INVENTION

The present invention is an improved implantable medical device comprised of a tubular, radially compressible, axially flexible and radially self-expandable structure including elongate filaments formed in a braid-like configuration. The filaments consist of a bioabsorbable polymer which exhibits a relatively high degree of biocompatibility.

Briefly, self-expanding stents of the present invention are formed from a number of resilient filaments which are helically wound and interwoven in a braided configuration. The stents assume a substantially tubular form in their unloaded or expanded state when they are not subjected to external forces. When subjected to inwardly directed radial forces the stents are forced into a reduced-radius and extended-length loaded or compressed state. The stents are generally characterized by a longitudinal shortening upon radial expansion.

In one preferred embodiment, the device is a stent which substantially consists of a plurality of elongate polylactide bioabsorbable polymer filaments, helically wound and interwoven in a braided configuration to form a tube. Bioabsorbable implantable endoprostheses such as stents, stent-grafts, grafts, filters, occlusive devices, and valves may be made of poly(alpha-hydroxy acid) such as poly-L-lactide (PLLA), poly-D-lactide (PDLA), polyglycolide (PGA), polydioxanone, polycaprolactone, polygluconate, polylactic acid-polyethylene oxide copolymers, modified cellulose, collagen, poly(hydroxybutyrate), polyanhydride, polyphosphoester, poly(amino acids), or related copolymers materials, each of which have a characteristic degradation rate in the body. For example, PGA and polydioxanone are relatively fast-bioabsorbing materials (weeks to months) and PLA and polycaprolactone are a relatively slow-bioabsorbing material (months to years).

A stent constructed of a bioabsorbable polymer provides certain advantages relative to metal stents such as natural decomposition into non-toxic chemical species over a period of time. Also, bioabsorbable polymeric stents may be manufactured at relatively low manufacturing costs since vacuum heat treatment and chemical cleaning commonly used in metal stent manufacturing are not required.

The present invention includes a method of designing and manufacturing an improved braided bioabsorbable stent which is different from practices used to make braided metal wire stents. The method involves selecting a specific bio-

absorbable polymer based on a desired stent functional absorption time and stent radial force. The stent functional absorption time is the time period within which the stent retains at least 80% of its original radial strength. The stent is made by first selecting a braid design from the invention and making two different annealed stents. Radial force and dimensional test results from the two stents are used to develop a nearly linear mathematical equation to determine the parameters to meet the design goals. This method advantageously limits costly and time consuming trial and error to arrive at the optimum design.

Bioabsorbable polymer stents are radiolucent and the mechanical properties of the polymers are generally lower than structural metal alloys. Bioabsorbable stents may require radiopaque markers and may have a larger profile on a delivery catheter and in a body lumen to compensate for the lower material properties.

Bioabsorbable PLLA and PGA material are degraded in vivo through hydrolytic chain scission to lactic acid and glycolic acid, respectively, which in turn is converted to CO_2 and then eliminated from the body by respiration. Heterogeneous degradation of semicrystalline polymers occurs due to the fact that such materials have amorphous and crystalline regions. Degradation occurs more rapidly at amorphous regions than at crystalline regions. This results in the product decreasing in strength faster than it decreases in mass. Totally amorphous, cross-linked polyesters show a more linear decrease in strength with mass over time as compared to a material with crystalline and amorphous regions. Degradation time may be affected by variations in chemical composition and polymer chain structures, and material processing.

PLA monofilaments may be produced by a process involving seven general steps as summarized herein. First, a polymer formed of poly-L-lactic acid is brought to an elevated temperature above the melting point, preferably 210°–230° C. Second, the material is then extruded at the elevated temperature into a continuous fiber, by a conventional process, at a rate about of three to four feet per minute. Third, the continuous fiber is then cooled to cause nucleation. The cooling is preferably performed by passing the fiber through a nucleation bath of water. Fourth, the material then passes through a first puller, which runs at about the same speed as the extruder, and places the material under slight tension. Fifth, the fiber is then heated to a temperature between about 60° C. and about 90° C. (preferably 70° C.) as it passes through a heated oven. To perform annealing, the oven can be designed to be quite long and heated near the end, so that the orientation and annealing take place in the same oven. Alternatively, a separate oven can be placed directly after the orientation oven. The annealing step heats the fibers to a range of about 65° C. to about 90° C., preferably closer to 90° C. Sixth, while being heated in the orientation oven and the annealing oven, the fiber is drawn between the first puller located before the orientation oven and a second puller located after the annealing oven (if a separate oven). The material is drawn at a draw ratio of between about 5 to about 9, preferably between about 6 and about 8. Draw ratio describes the extension in length resulting from polymer extrusion or drawing. Quantitatively, the drawing ratio is a unitless value equal to the extruded or drawn length divided by the original length. Maintaining tension through the annealing step prevents shrinkage in later use. The second puller, located at the exit of the oven, runs at an increased speed necessary to provide the desired draw ratio. As the fiber exits the oven and passes through the second puller the tension is immediately released before the material cools. Seventh, finally, the fiber is collected onto spools of desired lengths.

Strength of the filaments generally increases with draw ratio and with lower draw temperatures. A draw ratio of between 5 and 9 is preferred. PLA is generally amorphous because of the material's slow crystallization kinetics. Very slow cooling after drawing of the filament or use of a nucleating agent will cause crystallization. However, the material may be annealed at temperatures above about 60° C. to cause crystallization, and generally, the strength decreases slightly and the modulus increases. Annealing is preferably performed after drawing to release residual stresses and to homogenize the surface to center variations in structure. Annealing will preferably be performed at a temperature of between about 60° C. and 150° C. for a period of time between about 5 and 120 minutes. Reference is made to *Enhancement of the Mechanical properties of polylactides by solid-state* extrusion, W. Weiler and S. Gogolewski, Biomaterials 1996, Vol 17 No. 5, pp. 529–535; and *Deformnation Characterstics of a Bioabsorbable Intravascular Stent*, Investigative Radiology, December 1992, C. Mauli, Agrawal, Ph.d., P.E., H. G. Clark, Ph.D., pp. 1020–1024. It is generally preferred in accordance with this invention that the annealed bioabsorbable filament has a substantially homogeneous cross-section, in other words, that it has a substantially solid cross-section without substantial variations between the center and the surface of the filament.

Mechanical properties generally increase with increasing molecular weight. For instance, the strength and modulus of PLA generally increases with increasing molecular weight. Degradation time generally decreases with decreasing initial molecular weight (i.e., a stent made of a low molecular weight polymer would be bioabsorbed before a stent made of a high molecular weight polymer). Low molecular weight PLA is generally more susceptible to thermo-oxidative degradation than high molecular weight grades, so an optimum molecular weight range should be selected to balance properties, degradation time, and stability. The molecular weight and mechanical properties of the material generally decreases as degradation progresses. PLA generally has a degradation time greater than 1 year. Ethylene oxide sterilization process (EtO) is a preferred method of sterilization. PLA has a glass transition temperature of about 60° C., so care must be taken not to store products in environments where high temperature exposure may result in dimensional distortion.

PLA, PLLA, PDLA and PGA include tensile strengths of from about 40 thousands of pounds per square inch (ksi) to about 120 ksi; a tensile strength of 80 ksi is typical; and a preferred tensile strength of from about 60 ksi to about 120 ksi. Polydioxanone, polycaprolactone, and polygluconate include tensile strengths of from about 15 ksi to about 60 ksi; a tensile strength of 35 ksi is typical; and a preferred tensile strength of from about 25 ksi to about 45 ksi.

PLA, PLLA, PDLA and PGA include tensile modulus of from about 400,000 pounds per square inch (psi) to about 2,000,000 psi; a tensile modulus of 900,000 psi is typical; and a preferred tensile modulus of from about 700,000 psi to about 1,200,000 psi. Polydioxanone, polycaprolactone, and polygluconate include tensile modulus of from about 200,000 psi to about 700,000 psi; a tensile modulus of 450,000 psi is typical; and a preferred tensile modulus of from about 350,000 psi to about 550,000 psi.

PLLA filament has a much lower tensile strength and tensile modulus than, for example Elgiloy® metal alloy wire

which may be used to make braided stents. The tensile strength of PLLA is about 22% of the tensile strength of Elgiloy®. The tensile modulus of PLLA is about 3% of the tensile modulus of Elgiloy®. Stent mechanical properties and self-expansion are directly proportional to tensile modulus of the material. As a result, a PLLA filament braided stent made to the same design as the metal stent has low mechanical properties and would not be functional. The invention advantageously provides polymeric braided stents with radial strength similar to metal stents and the required mechanical properties capable of bracing open endoluminal strictures.

A bioabsorbable PLLA braided tubular stent changes size when constrained onto a catheter delivery system and when deployed. A deployed PLLA stent is generally longer in length and smaller in diameter than a PLLA stent prior to loading. For example, PLLA stents that were initially 30 mm long with external diameters of about 10.7 mm had deployed lengths of about 90 mm with diameters of about 6.3 mm.

In comparison, a metal self-expanding stent generally has about the same dimensions before loading and after deployment. For metal stents, if it is known that the patient has a 9 mm diameter vessel, then a 10 mm metal stent (stent is intentionally oversized by about 1 mm) is loaded onto the delivery system for implantation. This rule is not applicable for a polymer stent because more oversizing is necessary.

The present invention provides improved polymeric stents and a method for designing and producing the improved polymeric stents whereby a polymeric stent of a certain size may be produced, loaded on the delivery system, and upon deployment will yield desired implant dimensions and have desired mechanical properties.

The present invention advantageously provides a bioabsorbable PLLA braided stent of a desired implant size, and provides a method to make the stent at a particular diameter (A), anneal the stent at a smaller diameter (B), and deploy the stent from a delivery system of diameter (C) whereby the stent will be "programmed" to self-expand to a desired implant diameter (D). The relationship between the diameters is A>B>D>C.

In sum, the invention relates to a bioabsorbable implantable stent having a tubular, radially compressible and self-expandable braided and annealed structure including a first set of between 5 and 18 filaments, each of which extends in a helix configuration along a center line of the stent and having a first common direction of winding. A second set of filaments of the same number as the first set, each extend in a helix configuration along a center line of the stent and having a second common direction of winding. The second set of filaments cross the first set of filaments at an axially directed angle of between about 120 and about 150 degrees when in a first free radially expanded state after being annealed, but before being loaded on a delivery device so as to form a plurality of interstices between filaments. The term "free state" is used when no externally applied forces are acting on the device, for example, when the device is resting on a table. Each filament includes PLLA, PDLA, PGA, or combinations thereof and have a substantially solid and substantially uniform cross-section, a tensile strength of from about 40 ksi to about 120 ksi, a tensile modulus of from about 400,000 psi to about 2,000,000 psi, and an average diameter of from about 0.15 mm to about 0.6 mm. The first set of filaments and second set of filaments act upon one another to create an outwardly directed radial force sufficient to implant the stent in a body vessel upon deployment from a delivery device. The stent may have a second free radially expanded state after being loaded and then released from a deployment device and the first and second sets of filaments cross at an axially directed angle of between about 80 and about 145 degrees when in the second free radially expanded state. The second sets of filaments may crisscross at an axially directed angle of between about 90 and about 100 degrees when in the second free radially expanded state, and a second free state diameter of from about 3 mm to about 6 mm. The axially directed angle may be between about 110 degrees and about 120 degrees when in the second free radially expanded state. The stent may have an outside diameter when in the second free radially expanded state and the stent exerts an outwardly directed radial force at one half of the outside diameter of from about 40 grams to about 300 grams. The stent may have an implanted state after being loaded, released from a deployment device into a body vessel, and then implanted in the body vessel, with the first and second sets of filaments crossing at an axially directed angle of between about 95 and 105 degrees when the stent is in the implanted state. The stent may be radially constrained to half of its free diameter and the radial force, RF, exerted by the device, in grams, as a function of annealed diameter, D, in mm, is about RF=−15D+491±20. The stent may be annealed at a temperature of from about 60° C. to about 180° C. for a period of time of from about 5 minutes to about 120 minutes. The stent may be annealed at a temperature of from about 130° C. to about 150° C. for a period of time of from about 10 minutes to about 20 minutes. The braid may be annealed to yield a crossing angle of from about 130 degrees to about 150 degrees. The stent may be further disposed in a stent delivery device and the filaments have a crossing angle of from about 30 degrees to about 120 degrees. The stent may be deployed from a delivery system into a body lumen and the filaments have a crossing angle of from about 70 degrees to about 130 degrees. The stent may provide structural integrity to a body lumen for less than about 3 years. The stent may further include polydioxanone, polycaprolactone, polygluconate, polylactic acid-polyethylene oxide copolymers, modified cellulose, collagen, poly(hydroxybutyrate), polyanhydride, polyphosphoester, poly(amino acids) and combinations thereof. The filaments may be mono-filament or multi-filament. The stent may substantially degrade in vivo in from about 1 year to about 2 years. "Substantially degrade" means that the stent has lost at least 50% of its structural strength. It is preferable that the stent lose about 100% of its structural strength. The filaments may include polyglycolide and the stent may substantially degrades in vivo in a time of from about 3 months to about 1 year. The filaments may further include polygluconate, polydioxanone, or combinations thereof and the stent may substantially degrade in vivo in from about 1 week to about 3 months. The stent may have at least one end of diminishing diameter so as to function as a filter. The filaments may be substantially homogeneous in cross section and length. The filaments may have a tensile modulus of from about 400,000 psi to about 1,200,000 psi. The filaments may have a tensile modulus of from about 700,000 psi to about 1,200,000 psi. The stent may includes a plurality of the filaments helically wound and interwoven in a braided configuration to form a tube.

The invention also relates to a method of using an implantable endoprosthesis including: providing a tubular, radially compressible, axially flexible, and radially self-expandable braided and annealed structure. The structure including from about 10 to about 36 elongate filaments. The filament comprising PLLA, PDLA, PGA, and combinations thereof. Each filament having a substantially uniform cross-

section, a tensile strength of from about 40 ksi to about 120 ksi, and a tensile modulus of from about 400,000 psi to about 2,000,000 psi. The filaments disposed at an angle of from about 130 degrees to about 150 degrees in a free state, each filament having an average diameter of from about 0.15 mm to about 0.6 mm, and the stent having a radial force at one-half diameter of from about 40 grams to about 300 grams. The annealed structure having a first diameter; disposing the structure into a delivery system at a second diameter smaller than the first diameter; inserting the delivery system and endoprosthesis in a body lumen; deploying the endoprosthesis from the delivery system into the body lumen to a third diameter smaller than the first; and allowing the endoprosthesis to self expand in the body lumen to a fourth diameter greater than the third diameter.

The invention also relates to a method for treating a site within a vessel of a patient, including: providing a biocompatible medical device including a tubular and axially flexible braid-like annealed structure at a first diameter which is radially self-expandable between a compressed state and an expanded state and which includes from about 10 to about 36 elongate filaments. The filaments include PLLA, PDLA, PGA, and combinations thereof. Each filament has a substantially uniform cross-section, a tensile strength of from about 40 ksi to about 120 ksi, and a tensile modulus of from about 400,000 psi to about 2,000,000 psi; Providing a delivery system with the medical device positioned on a portion of the delivery system in the compressed state at a second diameter smaller than the first diameter, Inserting the portion of the delivery system with the medical device into the patient's vessel at a location spaced from the treatment site, and manipulating the delivery system to advance the medical device through the vessel, to the treatment site; Deploying the medical device from the delivery system. The medical device being deployed at a third diameter smaller than the original free diameter and allowing the medical device to self-expand within the vessel; and Removing the delivery system from the patient with the medical device remaining in the expanded state and supporting the vessel.

The invention also relates to a bioabsorbable implantable device made from the process including providing a plurality of elongate filaments including PLLA, PDLA, PGA, and combinations thereof; braiding the filaments on a first mandrel to form a tubular, radially compressible, axially flexible, and radially self-expandable device. The device having a first diameter of from about 2 mm to about 10 mm larger than the final implanted device diameter; and annealing the device on a second mandrel having a second diameter smaller than the first diameter. The second mandrel diameter adapted to be computed from a linear equation relating radial force to annealed stent diameter. The equation being derived from measured radial force and measured annealed stent diameter data from two stent prototypes made on two anneal mandrel diameters and deployed from a device delivery system. Each filament may have a substantially uniform cross-section, a tensile strength of from about 40 ksi to about 120 ksi, and a tensile modulus of from about 400,000 psi to about 2,000,000 psi. Annealing may cause the device to radially shrink.

The invention also relates to a method of manufacturing a stent including: providing from about 10 to about 36 filaments consisting essentially of poly (alpha-hydroxy acid). The filaments have an average diameter from about 0.15 mm to about 0.60 mm; braiding the filaments at a braid angle of from about 120 degrees to about 150 degrees on a braid mandrel of from about 3 mm to about 30 mm diameter ; removing the braid from the braid mandrel; disposing the braid on an annealing mandrel having an outer diameter of from about 0.2 mm to about 10 mm smaller than the braid mandrel diameter; annealing the braid at a temperature between about the polymer glass-transition temperature and the melting temperature for a time period between about 5 and about 120 minutes; and allowing the stent to cool.

Bioabsorbable polymer resins are commercially available. Bioabsorbable resins such as PLA, PLLA, PDLA, PGA and other bioabsorbable polymers are commercially available from several sources including PURAC America, Inc. of Lincolnshire, Ill.

Still other objects and advantages of the present invention and methods of construction of the same will become readily apparent to those skilled in the art from the following detailed description, wherein only the preferred embodiments are shown and described, simply by way of illustration of the best mode contemplated of carrying out the invention. As will be realized, the invention is capable of other and different embodiments and methods of construction, and its several details are capable of modification in various obvious respects, all without departing from the invention. Accordingly, the drawing and description are to be regarded as illustrative in nature, and not as restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an isometric view of a stent in accordance with the present invention, illustrating the braided configuration of the filaments;

FIG. **2** is a partial longitudinal cross-sectional view of the stent shown in FIG. **1**;

FIG. **3** is a cross-sectional view of one of the filaments of the stent shown in FIG. **1**;

FIG. **4** is a side view of a delivery device with the stent shown in FIG. **1** loaded thereon;

FIG. **5** is a detailed view of the portion of the delivery device encircled at 5 in FIG. **4**;

FIG. **6** is a detailed view of the portion of the delivery device encircled at 6 in FIG. **4**;

FIGS. **7–10** are partial cross-sectional side views of the distal portion of the delivery device and stent shown in FIG. **4** at various stages during a stent deployment operation in a body vessel;

FIG. **11** is a side view of a pusher-type delivery device;

FIG. **12** is a side view of a second embodiment of a stent in accordance with the present invention;

FIG. **13** is an end view of the stent shown in FIG. **14**;

FIG. **14** is a plot illustrating PLLA stent radial force and deployed diameter vs. annealed stent diameter; and

FIGS. **15–18** are graphs of fatigue test results of PLLA filament batches.

DETAILED DESCRIPTION OF THE DRAWINGS

A bioabsorbable implantable prosthesis or stent **10** in accordance with the present invention is illustrated generally in FIGS. **1** and **2**. Stent **10** is a tubular device formed from two sets of oppositely-directed, parallel, spaced-apart and helically wound elongated strands or filaments **12**. The sets of filaments **12** are interwoven in an over and under braided configuration intersecting at points such as **14** to form an open mesh or weave construction. As described in greater detail below, at least one and preferably all filaments **12** consists of one or more commercially available grades of polylactide, poly-L-lactide (PLLA), poly-D-lactide (PDLA),

polyglycolide (PGA), polydioxanone, polycaprolactone, polygluconate, polylactic acid-polyethylene oxide copolymers, modified cellulose, collagen, poly (hydroxybutyrate), polyanhydride, polyphosphoester, poly (amino acids), poly(alpha-hydroxy acid) or related copolymers materials. Methods for fabricating stents **10** are generally known and disclosed, for example, in the Wallsten U.S. Pat. No. 4,655,771 and the Wallsten et al. U.S. Pat. No. 5,061,275.

Stent **10** is shown in its expanded or relaxed state in FIGS. **1** and **2**, i.e., in the configuration it assumes when subject to no external loads or stresses. The filaments **12** are resilient, permitting the radial compression of stent **10** into a reduced-radius, extended-length configuration or state suitable for delivery to the desired placement or treatment site through a body vessel (i.e., transluminally). Stent **10** is also self-expandable from the compressed state, and axially flexible.

Stated another way, stent **10** is a radially and axially flexible tubular body having a predetermined diameter that is variable under axial movement of the ends of the body relative to each other. The stent **10** is composed of a plurality of individually rigid but flexible and elastic thread elements or filaments **12**, each of which extends in a helix configuration along a longitudinal center line of the body as a common axis. The filaments **12** define a radially self-expanding body. The body may be provided by a first number of filaments **12** having a common direction of winding but axially displaced relative to each other, and crossing a second number of filaments **12** also axially displaced relative to each other but having an opposite direction of winding.

The tubular and self-expandable body or structure formed by the interwoven filaments **12** is a primary prosthetically-functional structure of stent **10**, and for this reason the device can be considered to substantially consist of this structure to the exclusion of other structures. However, it is known that other structures and features can be included in stents, and in particular features which enhance or cooperate with the tubular and self-expandable structure or which facilitate the implantation of the structure. One example is the inclusion of radiopaque markers on the structure which are used to visualize the position of the stent through fluoroscopy during implantation. Another example is the inclusion of a covering **15** or additional interwoven filaments, for instance, to reduce the porosity or open spaces in the structure so that the stent can be used to prevent tissue in growth or be used as a graft. Other examples include collapsing threads or other structures to facilitate repositioning and removal of the stent. Stents of these types nonetheless still substantially consist of the tubular and self-expandable structure formed by interwoven filaments **12** and shown in FIGS. **1** and **2**. Furthermore, many of the desirable features and properties of stent **10** will be present if some, but not all, of the filaments **12** consist of a bioabsorbable polymeric material.

An implantable bioabsorbable stent **10** may be made by a preferred method of braiding such that 10–36 independent strands of 0.15–0.60 mm diameter bioabsorbable polymeric filament are interwoven into helical shape strands on a round bar mandrel of 3–30 mm diameter such that one-half of the number of helical strands are wound clockwise and one-half are wound counterclockwise and such that each clockwise helical strand is adjacent (interbraided) to a counterclockwise strand, the tubular braid is made with strand braid angles (angle between two filaments in the longitudinal or axial direction) of 120–150 degrees (pitch angles (angle between a filament and transverse axis of the stent) of 15–45 degrees) while on the braid bar mandrel, the braid is slid off of the braid bar and onto a 0.2–10 mm smaller diameter annealing bar or tube mandrel, each end of the braid pulled or compressed to cause axial extension or compression of the braid on the anneal mandrel, or left free, and each end of the braid secured on each end of the anneal mandrel to fix the preset axial position of the braid, or left free, annealing the braid on the anneal mandrel at a temperature between the glass-transition temperature and melting temperature of the polymer for 5–120 minutes in air, vacuum, or inert atmosphere, cooling the annealed braid on the anneal mandrel to about room temperature, sliding the braid off of the anneal mandrel and cutting it to the desired stent length. Another preferred embodiment includes at least one bioabsorbable-radiopaque marker strand.

FIG. **3** is a cross-sectional view of one of the polymeric filaments **12**. As shown, the filaments **12** are substantially homogeneous in cross section.

EXAMPLE 1

Four batches (**53**, **54**, **55**, **56**) of PLLA monofilament **12** were produced by the supplier, Albany International Research Corporation included eight strands collected on separate spools. Four spools were randomly selected from each batch and tested by the supplier. Processing information and supplier test results are set forth below in Table 1.

TABLE 1

Filament Spool No.	Average Diameter, mm	Diameter Standard, Deviation.	Mean Inherent Viscosity Of As Received Filament, Deciliter per gram (dl/g)	Processing History DR = Draw Ratio
53-1	.233	.005	2.89	final DR = 6
53-3	.240	.005	2.98	final DR = 6
53-6	.240	.005	2.86	final DR = 6
53-8	.252	.007	2.78	final DR = 6
54-1	.232	.007	3.23	final DR = 8
54-3	.220	.007	3.31	final DR = 8
54-4	.234	.007	3.22	final DR = 8
54-6	.239	.006	3.14	final DR = 8
55-1	.236	.007	3.29	DR of 8 and mill anneal
55-3	.227	.008	3.32	DR of 8 and mill anneal

TABLE 1-continued

Filament Spool No.	Average Diameter, mm	Diameter Standard, Deviation.	Mean Inherent Viscosity Of As Received Filament, Deciliter per gram (dl/g)	Processing History DR = Draw Ratio
55-4	.248	.007	3.28	DR of 8 and mill anneal
55-6	.241	.006	3.20	DR of 8 and mill anneal
56-1	.237	.016	2.86	final DR of 8 and high extrusion temp.
56-4	.247	.009	2.82	final DR of 8 and high extrusion temp.
56-5	.243	.011	2.83	final DR of 8 and high extrusion temp.
56-6	.246	.009	2.86	final DR of 8 and high extrusion temp.

One spool from each batch was randomly selected for further testing. The PLLA filaments produced in spools **538, 544, 558,** and **568** were tested for their mechanical properties in the condition received from the supplier and again tested in an annealed condition. Testing included measurement of the filament diameter, tensile testing, and rotating beam-type fatigue testing. Measurements of mean filament properties in an as-received condition are summarized in Table 2 and measurements of mean filament properties after annealing at 140° C. for 15 minutes are summarized in Table 3.

TABLE 2

Spool #	Diameter, mm	Ultimate Tensile Strength (UTS), MPa	0.2% offset Yield Strength (YS), MPa	% Elongation at break	Modulus, MPa
53-8	.251	384	162	23.5	7102
54-6	.231	628	203	22.6	8826
55-6	.226	676	190	27.6	7447
56-6	.221	659	191	31.7	6550

TABLE 3

Spool #	Diameter, mm	Ultimate Tensile Strength (UTS), MPa	0.2% Offset Yield Strength (YS), MPa	% Elongation at break	Modulus, MPa
53-8	.236	655	141	37.3	3448
54-6	.231	605	181	29.4	6826
55-6	.229	642	181	30.2	6619
56-6	.236	615	172	34.0	5378

Experimentation shows that the diameters of the strands did not change substantially after annealing. The tensile breaking loads were lowest for batch **#53** which was drawn at the lowest drawing ratio of 6. The break loads for all four batches ranged from about 4 to 6 lbs. (18 to 28 N) before annealing and the break loads were about the same range after annealing. The mean breaking load was highest for batch **#55** which was mill annealed after the final draw ratio of 8. However, after annealing, the difference in mean break loads in the three batches extruded with a draw ratio of 8 was not significant. The mean tensile elongation was highest for batch **#56** which was extruded at a higher temperature. The tensile modulus values (Young's modulus) were about one million psi (8000 Mpa) prior to annealing and the tensile modulus values were slightly reduced after annealing, with the exception of batch **#53** (DR=6) where the tensile modulus was nearly reduced in half. There were no significant changes in strength or modulus as a result of the annealing at 140° C. for 15 minutes. The annealing was performed to relax and homogenize the material after braiding and to allow the braid to shrink to the desired annealed stent diameter.

Rotating beam bending fatigue testing was performed on annealed specimens from each of the four batches. Testing of the as-extruded filaments was unsuccessful because the filaments did not appear stiff enough to be capable of withstanding torsional loading. However, testing was performed using the Valley Instruments U-bend wire spin fatigue machines. One end of the test specimen was gripped by a chuck, the specimen was formed into an arc, and the free end was inserted into a stationary holder to maintain the arc. The arc dimensions and material modulus were used to

calculate the maximum bending stress at the apex of the arc. The specimen was then rotated at 3600 rpm and the surface of the test specimen is cycled between compressive and tensile bending stresses at the apex of the arc. The number of cycles to failure (complete fracture, kinking, or longitudinal splitting) was recorded for each test, and the results are plotted in a stress vs. cycles to failure plot (S/N fatigue plots in FIGS. **15–18**).

Batch **#53**, with the lowest draw ratio of 6, had lower fatigue results or failures at lower stresses than the batches extruded at the higher draw ratio of 8. Batches **#54** and **#55** had similar fatigue results, and batch **#56** had lower results than **#54** and **#55**, but had higher results than 53. The results indicate that the higher draw ratio and lower extrusion temperatures are preferred if fatigue strength is to be maximized.

EXAMPLES 2–10

A stent **10** was fabricated from about 0.24 mm diameter PLLA monofilament **12** from spool **55-6**. This spool was selected because it had high UTS and modulus which are desirable mechanical properties for obtaining high stent radial strength. The stent **10** was braided onto a 10 mm diameter steel bar mandrel. The braid was constructed of 24 strands and the braid angle was 130 degrees (pitch angle of 25 degrees). The included angle between interbraided filaments in the axial orientation is termed "braid angle" prior to annealing and is termed "filament crossing angle" after annealing. A braid becomes a stent after annealing.

Braid annealing was performed to relax the stresses in the filaments resulting from braiding and to set the stent shape. Three anneal trials were performed. In the first trial, the braid was slid onto a 10 mm diameter tubular mandrel. In this trial, the braid was difficult to put on the mandrel because the braid inside diameter was very close to the mandrel diameter. In the second trial, the braid was easily put onto a 9 mm diameter mandrel. The braid was compressed axially and held in this state with plastic tie-wraps. The third trial was performed in the same manner as the second trial.

After annealing, the braid had shrunk down onto the anneal mandrel and the annealed filament crossing angle was higher than the original braid angle. The annealed uncut stents were measured with a laser micrometer for external diameter. A scale was used to measure pitch length. The results are presented in the following Table 4.

TABLE 4

Dimension	Trial #1	Trial #2	Trial #3
Average External Diameter, mm	10.65	9.83	9.87
Pitch Length, mm	10.34	10.34	10.08
Calculated Filament Crossing Angle, °	145	143	144

The average external diameter is the average value of the external stent diameters measured. The pitch length is the length of one complete filament helix. The filament crossing angle was calculated from the average external diameter and the pitch length using the equation, angle=$180°-2\ \mathrm{Tan}^{-1}(P/\pi D)$, where p is the pitch length and D is the average external stent diameter minus twice the filament diameter.

The uncut stents **10** were then cut to 30 mm lengths at the free diameter and were loaded onto 10 French catheter delivery systems. The delivery system is constructed of an inner tube which slides over the guidewire in an angioplasty procedure and an outer tube. The stent is axially extended and radially contracted onto the outer surface of the inner tube and the outer tube is slid coaxially over the constrained stent to hold it in the constrained condition. When the delivery system is positioned in the stricture to be treated, the outer tube is pulled back allowing the stent to spring off of the inner tube and self-expand to brace open the stricture. The nominal outer tube inner diameter was 2.8448 mm and the inner tube outer diameter was 1.3208 mm. The calculated gap between the inner and outer tube was 0.7642 mm. The stents **10** were left on the delivery systems for 30 minutes and were then were deployed onto the benchtop.

Dimensions of the nine 10 mm PLLA stents **10** before loading and after deployment are listed in Table 5.

TABLE 5

Trial #	Initial Length, mm	Deployed Length, mm	Initial Diameter, mm	Deployed Diameter, mm	Self-expansion (deployed/initial Ø)
1a	32	90	10.69	6.2	0.58
1b	30	88	10.73	6.6	0.62
1c	30	90	10.63	6.2	0.58
2a	30	80	9.94	5.2	0.52
2b	30	68	9.83	6.2	0.63
2c	30	80	9.88	6.4	0.65
3a	30	80	9.96	5.0	0.50
3b	30	80	9.76	5.7	0.58
3c	30	80	9.80	5.6	0.57

Initial length and diameter were measured on the cut stent in its free state on the table after annealing but before being loaded for deployment. Deployed length and diameter were measured after the annealed stent was loaded on the 10 French delivery system and deployed on the table and allowed to reach its free state. The lengths of-stents upon implantation will be longer upon implantation because the stent will only reach about 80% of the deployed diameter when implanted.

The stent dimensional changes resulting from loading appeared consistent from test specimen to test specimen. The stents **10** were deformed by the constraint on the delivery system. This consistency allows the dimensional changes to be anticipated and accounted for during design. The dimensions of deployed stents **10** were considerably changed relative to the dimensions of the same stents **10** prior to loading. The deformation was not permanent and the

stents **10** reverted toward the original dimensions over a period of days after deployment. For instance, the stents **10** from trial **#1** opened up to almost 90% of their original pre-loaded diameter after about 3 days from the deployment time.

Residual stresses appear to remain in the material from delivery system constraint and are relieved at room temperature over a period of time which allows stent **10** to return toward its original undeformed condition. If the residual stresses can be minimized, or if the magnitude of the residual stresses relative to the yield strength can be minimized, or if stress relief can be accelerated to seconds instead of days, it may be possible to increase the amount of self-expansion immediately upon deployment. In order to avoid imparting significant residual stresses, loading is preferably performed with less stressing of the stent **10**, i.e., use of a larger profile delivery system, use of a larger gap between inner and outer tubes, a gentle loading technique, or use of an alternate delivery system design.

The use of a pusher-type delivery system results in greater self-expansion of the stent than a coaxial inner-outer tube-type delivery system as shown in FIG. **11**. Reference is made to U.S. Pat. No. 4,954,126. For example, pushing the proximal end of the stent out the distal end of the delivery system results in more self expansion than when the stent is released by sliding back the outer tube of the catheter delivery system because the stent **10** is under axial compression during deployment.

EXAMPLE 11–15

Experiments were performed using various PLLA monofilament braided stents **10**. The stents **10** were annealed on various sized tubular anneal mandrels and then loaded and deployed from delivery systems. The 36 French delivery systems pushed the stent **10** out of a stainless steel outer tube. The 10 and 18 French delivery systems were inner and outer tube catheter type systems where the outer tube is pulled back to allow the stent to spring open. The external diameter of the stents **10** were measured after annealing and after deployment from the delivery system. Radial force testing was performed on deployed stents **10** by wrapping a metal wire around the stent circumference at the center of the stent length and pulling on each end of the wire to cause radial contraction of the stent diameter to one-half of its original (free) value. The ends of the wire were attached to a load cell to measure the force necessary to cause radial contraction. The braid mandrel diameter is the external diameter of the braid bar. The delivery system size is the external diameter in French size (or about three times the diameter in mm). Deployed stent external diameter and radial force were measured on stents released from the delivery system onto the table. Percent self-expansion is (deployed diameter/annealed diameter)×100.

The experimental results for PLLA braided stent load and deployment trials and radial force testing are shown in Table 6 below The inner/outer tube catheter type of delivery system yielded lower percent self-expansion than the pusher type of delivery system (58–76% vs. 85–93%, respectively).

TABLE 6

# Of Filaments In Braid	Filament Diameter, Mm	Braid Mandrel Dia., Mm	Anneal Mandrel Dia., Mm	Annealed Stent External Dia., Mm	Delivery System Size, French	Deployed Stent External Dia., Mm	Percent Self-Expansion	Radial Force At Half-Stent Dia. Grams
24	.25	10.0	9.0	9.9	10	5.7	58	64
30	.35	18.5	18.0	19.1	18	14.5	76	90
36	.36	25.8	18.0	19.4	36	16.4	85	200
36	.36	25.8	22.0	23.3	36	19.7	85	132
36	.36	25.8	24.0	25.2	36	23.4	93	113

Experimentation has shown that there is a nearly linear relationship between stent radial force and annealed stent diameter for a given braid design and delivery system design. The present invention provides a method to determine the preferred anneal mandrel size for a particular polymeric stent **10** design. For example, if a PLEA braided filament stent **10** is desired to have a radial force equal to a particular metal stent or polymer stent, the radial force of the benchmark stent can be measured and used as the target value. Further, a stent **10** of a size at or about the desired implant size from Table 7 above would then be annealed on two different sizes of anneal mandrels and the radial force of the deployed annealed stents would be measured. The slope and intercept values would be calculated from the test results. The linear equation can then be used to solve for the annealed stent diameter which will yield the target radial force value. Example 16 below illustrates the methodology.

EXAMPLE 16

The radial force data in Table 6 for the 36-filament stents was plotted against the values for annealed stent diameter and is illustrated in FIG. **13** for stents **10** with 36 strands of 0.36 mm diameter PLLA filament annealed at 140° C. for 15 minutes and deployed from a 36 French pusher-type delivery system.

The graph is nearly linear. The slope and intercept were calculated using two sets of coordinates from the line (200 g, 19.4 mm and 113 g, 25.2 mm).

RF (g)=m (ann Ø)+b where m is the slope and b is the intercept.

Equation 1 (36-filament PLLA stent)

$$m = 200 - 113/19.4 - 25.2 = -15$$

$$200 = (-15)(19.4) + b \quad b = 491$$

$$RF(\text{g}) = (-15)(\text{ann } \emptyset) + 491$$

For example, if the target value for radial force is 150 g:

$$150 = (-15)(\text{ann } \emptyset) + 491$$

annealed stent diameter = 22.73 mm

-continued

anneal mandrel diameter = stent diameter − 4*d*

where *d* is the filament diameter

anneal mandrel diameter = 21.29 mm

Accordingly, it is possible to manufacture a bioabsorbable stent which is predicted to yield a desired radial force after deployment from the delivery system. For example, from Table 6 or 7, a stent **10** design of 36 strands has a 0.36 mm diameter PLLA filament. The stent **10** can be then annealed on a 21.29 mm diameter tubular mandrel. The annealed stent **10** can be loaded onto a 36 French pusher delivery system for implantation.

Similar experimentation was used to predict the deployed stent diameter (implant size) from the annealed stent diameter for a given braid design and delivery system size. A graph of the deployed stent diameter vs. annealed stent diameter is nearly linear, so a linear equation is used to predict the deployed stent diameter. Two stents **10** were made from two different anneal mandrel sizes and then loaded and deployed from the delivery system. The linear equation can be determined from the experimental results. Subsequently, the linear equation is used to predict the anneal mandrel size necessary to yield a target implant size.

EXAMPLE 17

The deployed stent diameter data in Table 6 for the 36-filament stents was plotted against the values for annealed stent diameter (FIG. **13**). The graph is nearly linear. The slope and intercept were calculated using two sets of coordinates from the line (16.4 mm, 19.4 mm and 23.4 mm, 25.2 mm).

deployed Ø=m (ann Ø)+b where m is the slope and b is the intercept.

Equation 2 (36-filament PLLA stent)

$m = 16.4 - 23.4/19.4 - 25.2 = 1.21$

$16.4 = (1.21)(19.4) + b \quad b = -7.07$

deployed Ø = (1.21) (ann Ø) − 7.07

For example, if the target value for deployed diameter is 20 mm: 20=(1.21)(ann Ø)−7.07

annealed stent diameter = 22.37 mm

anneal mandrel diameter = stent diameter − 4*d*

where *d* is the filament diameter

anneal mandrel diameter = 20.93 mm

Accordingly, the present invention provides a bioabsorbable stent which provides a desired radial force and diameter after deployment from the delivery system. For example, from Table 6 or 7, a stent **10** design of 36 strands has a 0.36 mm diameter PLLA filament The stent **10** can be annealed on a 20.93 mm diameter tubular mandrel and loaded onto a 36 French pusher delivery system for implantation. Furthermore, the stent **10** would yields a radial force of about 155 grams as previously shown.

Using linear equations to predict the annealed stent diameter and radial force minimizes the total number of design iterations for manufacturing and testing. Only two designs must be made to allow the predictive equations to be developed.

The PLLA filament stent **10** from Table 7 may be used with the required delivery system. The linear equations can be derived using the two test series, and thereafter the stent design may be optimized with regard to radial force and implant size by predicting the necessary anneal mandrel size.

TABLE 7

# of filament strands in stent	braid mandrel diameter, mm	braid angle degrees	PLLA diameter, mm	PDLA diamter, mm	PLLA/PDLA diameter, mm	PGA diamter, mm
10	3–6	120–150	.15–.25	.15–.25	.15–.25	.20–.30
10	3–6	120–150	.20–.30	.20–.30	.20–.30	.25–.35
12	3–8	120–150	.20–.30	.20–.30	.20–.30	.25–.35
12	3–8	120–150	.35–.45	.35–.45	.35–.45	.40–.50
15	6–10	120–150	.30–.40	.30–.40	.30–.40	.35–.45
15	6–10	120–150	.35–.45	.35–.45	.35–.45	.40–.50
18	7–12	120–150	.35–.45	.35–.45	.35–.45	.40–.50
18	7–12	120–150	.40–.50	.40–.50	.40–.50	.45–.55
20	3–9	120–150	.20–.30	.20–.30	.20–.30	.25–.35
24	8–12	120–150	.20–.30	.20–.30	.20–.30	.25–.35
24	9–14	120–150	.25–.35	.25–.35	.25–.35	.30–.40
24	12–18	120–150	.30–.40	.30–.40	.30–.40	.35–.45
30	16–26	120–150	.30–.40	.30–.40	.30–.40	.35–.45
36	20–30	120–150	.35–.45	.35–.45	.35–.45	.40–.50
24	14–20	120–150	.35–.45	.35–.45	.35–.45	.40–.50

# of filament strands in braid	braid mandrel diameter, mm	braid angle, degrees	PGA/PLLA diameter, mm	PGA/ polycaprolactone diameter, mm	Polydioxanone diameter, mm	PGA/trimethylene carbonate diameter, mm
10	3–6	120–150	.20–.30	.22–.32	.25–.35	.22–.32
10	3–6	120–150	.25–.35	.27–.37	.30–.40	.27–.37
12	3–8	120–150	.25–.35	.27–.37	.30–.40	.27–.37
12	3–8	120–150	.40–.50	.42–.52	.45–.55	.42–.52
15	6–10	120–150	.35–.45	.37–.47	.40–.50	.37–.47
15	6–10	120–150	.40–.50	.42–.52	.45–.55	.42–.52

TABLE 7-continued

18	7–12	120–150	.40–.50	.42–.52	.45–.55	.42–.52
18	7–12	120–150	.45–.55	.47–.57	.50–.60	.47–.57
20	3–9	120–150	.25–.35	.27–.37	.30–.40	.27–.37
24	8–12	120–150	.25–.35	.27–.37	.30–.40	.27–.37
24	9–14	120–150	.30–.40	.32–.42	.35–.45	.32–.42
24	12–18	120–150	.35–.45	.37–.47	.40–.50	.37–.47
30	16–26	120–150	.35–.45	.37–.47	.40–.50	.37–.47
36	20–30	120–150	.40–.50	.42–.52	.45–.55	.42–.52
24	14–20	120–150	.40–.50	.42–.52	.45–.55	.42–.52

The experiments indicate that stents **10** fabricated from the PLLA filament have desirable characteristics for certain applications. The stents **10** haste measurable resistance to compression and exert a more gentle force (less radial force) than the Elgiloy® stent on the lumen wall. Stents **10** are therefore durable and flexible, and capable of being moved through curved vessels or lumens during delivery. The PLLA material is highly biocompatible.

Although PLLA is the most preferred absorbable polymer, other polymers can also be used. In particular, poly-D-lactide (PDLA), polyglycolide (PGA), polydioxanone, polycaprolactone, polygluconate, polylactic acid-polyethylene oxide copolymers, modified cellulose, collagen, poly(hydroxybutyrate), polyanhydride, polyphosphoester, poly(amino acids), or related copolymers materials will offer advantages similar to the most preferred polymer.

EXAMPLE 18

Stents **10** can be fabricated from 10 filament strands of 0.15–0.25 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.20–0.30 mm diameter PGA, PGA-PLLA copolymer, 0.22–0.32 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.25–0.35 mm diameter polydioxanone on a 3–6 mm diameter braid mandrel with a filament braid angle of 120–150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2–10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5–120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel, cut to the desired stent length, and loaded onto a delivery system at least 5 French in size.

EXAMPLE 19

Stents **10** can be fabricated from 10 filament strands of 0.20–0.30 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.25–0.35 mm diameter PGA, PGA-PLLA copolymer, 0.27–0.37 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.30–0.40 mm diameter polydioxanone on a 3–6 mm diameter braid mandrel with a filament braid angle of 120–150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2–10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5–120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel, cut to the desired stent length, and loaded onto a delivery system at least 7 French in size.

EXAMPLE 20

Stents **10** can be fabricated from 12 filament strands of 0.20–0.30 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.25–0.35 mm diameter PGA, PGA-PLLA copolymer, 0.27–0.37 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.30–0.40 mm diameter polydioxanone on a 3–8 mm diameter braid mandrel with a filament braid angle of 120–150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2–10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5–120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature slid off the anneal mandrel, cut to the desired stent length, and loaded onto a delivery system at least 7 French in size.

EXAMPLE 21

Stents **10** can be fabricated from 12 filament strands of 0.35–0.45 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.40–0.50 mm diameter PGA, PGA-PLLA copolymer, 0.42–0.52 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.45–0.55 mm diameter polydioxanone on a 3–8 mm diameter braid mandrel with a filament braid angle of 120–150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2–10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5–120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel, cut to the desired stent length, and loaded onto a delivery system at least 10 French in size.

EXAMPLE 22

Stents **10** can be fabricated from 15 filament strands of 0.30–0.40 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.35–0.45 mm diameter PGA, PGA-PLLA copolymer, 0.37–0.47 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.40–0.50 mm diameter polydioxanone on a 6–10 mm diameter braid mandrel with a filament braid angle of 120–150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2–10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5–120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel, cut to the desired

stent length, and loaded onto a delivery system at least 8 French in size.

EXAMPLE 23

Stents **10** can be fabricated from 15 filament strands of 0.35–0.45 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.40–0.50 mm diameter PGA, PGA-PLLA copolymer, 0.42–0.52 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.45–0.55 mm diameter polydioxanone on a 6–10 mm diameter braid mandrel with a filament braid angle of 120–150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2–10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5–120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel, cut to the desired stent length, and loaded onto a delivery system at least 10 French in size.

EXAMPLE 24

Stents **10** can be fabricated from 18 filament strands of 0.35–0.45 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.40–0.50 mm diameter PGA, PGA-PLLA copolymer, 0.42–0.52 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.45–0.55 mm diameter polydioxanone on a 7–12 mm diameter braid mandrel with a filament braid angle of 120–150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2–10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5–120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel, cut to the desired stent length, and loaded onto a delivery system at least 10 French in size.

EXAMPLE 25

Stents **10** can be fabricated from 18 filament strands of 0.40–0.50 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.45–0.55 mm diameter PGA, PGA-PLLA copolymer, 0.47–0.57 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.50–0.60 mm diameter polydioxanone on a 7–12 mm diameter braid mandrel with a filament braid angle of 120–150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2–10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5–120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel, cut to the desired stent length, and loaded onto a delivery system at least 12 French in size.

EXAMPLE 26

Stents **10** can be fabricated from 20 filament strands of 0.20–0.30 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.25–0.35 mm diameter PGA, PGA-PLLA copolymer, 0.27–0.37 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.30–0.40 mm diameter polydioxanone on a 3–9 mm diameter braid mandrel with a filament braid angle of 120–150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2–10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5–120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel, cut to the desired stent length, and loaded onto a delivery system at least 9 French in size.

EXAMPLE 27

Stents **10** can be fabricated from 24 filament strands of 0.20–0–30 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.25–0.35 mm diameter PGA, PGA-PLLA copolymer, 0.27–0.37 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.30–0.40 mm diameter polydioxanone on a 8–12 mm diameter braid mandrel with a filament braid angle of 120–150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2–10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5–120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel, cut to the desired stent length, and loaded onto a delivery system at least 10 French in size.

EXAMPLE 28

Stents **10** can be fabricated from 24 filament strands of 0.25–0.35 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.30–0.40 mm diameter PGA, PGA-PLLA copolymer, 0.32–0.42 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.35–0.45 mm diameter polydioxanone on a 9–4 mm diameter braid mandrel with a filament braid angle of 120–150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2–10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5–120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel, cut to the desired stent length, and loaded onto a delivery system at least 12 French in size.

EXAMPLE 29

Stents **10** can be fabricated from 24 filament strands of 0.30–0.40 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.35–0.45 mm diameter PGA, PGA-PLLA copolymer, 0.37–0.47 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.40–0.50 mm diameter polydioxanone on a 12–18 mm diameter braid mandrel with a filament braid angle of 120–150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2–10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5–120 minutes in air, vacuum, or inert atmosphere with the braid in an axially

extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel, cut to the desired stent length, and loaded onto a delivery system at least 13 French in size.

EXAMPLE 30

Stents **10** can be fabricated from 30 filament strands of 0.30–0.40 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.35–0.45 mm diameter PGA, PGA-PLLA copolymer, 0.37–0.47 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.40–0.50 mm diameter polydioxanone on a 16–26 mm diameter braid mandrel with a filament braid angle of 120–150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2–10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5–120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel, cut to the desired stent length, and loaded onto a delivery system at least 14 French in size.

EXAMPLE 31

Stents **10** can be fabricated from 36 filament strands of 0.35–0.45 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.40–0.50 mm diameter PGA, PGA-PLLA copolymer, 0.42–0.52 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.45–0.55 mm diameter polydioxanone on a 20–30 mm diameter braid mandrel with a filament braid angle of 120–150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2–10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5–120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel, cut to the desired stent length, and loaded onto a delivery system at least 18 French in size.

EXAMPLE 32

Stents **10** can be fabricated from 24 filament strands of 0.35–0.45 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.40–0.50 mm diameter PGA, PGA-PLLA copolymer, 0.42–0.52 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.45–0.55 mm diameter polydioxanone on a 14–20 mm diameter braid mandrel with a filament braid angle of 120–150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2–10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5–120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel, cut to the desired stent length, and loaded onto a delivery system at least 14 French in size.

FIGS. **4–6** are illustrations of a coaxial inner/outer tube catheter delivery device **20** for delivering stent **10** to a treatment site in a body vessel. An extension to **45** from side port **41** to opening **42**.

As shown, stent **10** may be carried by the distal portion of delivery device **20**, and is placed on the delivery device in a radially contracted or compressed state. The proximal portion of delivery device **20** generally remains outside of the body for manipulation by the operator.

The manner by which delivery device **20** is operated to deliver stent **10** to a treatment site in a body vessel or lumen including curved sections is illustrated in FIGS. **7–10**. As shown, stent **10** is placed in a radially compressed state in a surrounding relationship to the outer distal end of inner tube **30**. A tip **31** is disposed at the distal end of tube **30**. Stent **10** is constrained on inner tube **30** by the double-walled section of hose **55**. It is important that stent **10** not be confined too tightly on inner tube **30**. Hose **55** should apply just enough force to stent **10** to hold stent **10** in place. The double-walled section of hose **55** can be removed from around stent **10** by pulling valve body **40** and proximal tube **50** in a proximal direction. The double-walled section "rolls" off stent **10**. No sliding movements take place between stent **10** and inner wall **56** which contacts stent **10**. Holes **59** are located in the double wall section of the holes **55**. Along with the movement of the double-walled section in a proximal direction, the distal end of stent **10** will be exposed in a radial direction to engagement against the wall of the body vessel. As the double-walled section of hose **55** continues moving proximally, more of stent **10** expands in a radial direction until the entire length of stent **10** is exposed and engages the wall of a body vessel.

Lumen **35** is used to enable delivery device **20** to follow a guide wire (not shown) previously inserted percutaneously into the body vessel. The lumen of inner tube **30** can also be used to introduce a contrast fluid to the area around the distal end of delivery device **20** so the position of delivery device **20** can be detected (e.g., through the use of fluoroscopy or X-ray techniques).

FIG. **11** illustrates a delivery device with an outer tube **61** including member **63** and an inner tube **62** including members **64, 65**. Stent **10** maybe disposed in region **66** and one position of member **65** is shown at about region **67**. Member **64** may move in the direction of arrow **68** to push the stent out through end **70** into contact with the interior of wall **72**. The stent **10** is shown as lines **69, 71**. The end **70** maybe moved by moving member **63** in the direction of arrow **73**.

The stents of the present invention may be delivered by alternative methods or using alternative devices. For instance, the device described in Heyn et al. U.S. Pat. No. 5,201,757 may be utilized.

Another embodiment of the present invention, stent **110**, is illustrated in FIGS. **12** and **13**. Stent **110** is similar to stent **10** described above in that it is a tubular device formed from two sets of oppositely-directed, parallel, spaced-apart and helically wound elongated strands or filaments **112**. The sets of filaments **112** are interwoven in an over and under braided configuration intersecting at points such as **114** to form an open mesh or weave construction. One end **116** of stent **110** is tapered and has a diameter which decreases from the diameter of the other portions of the stent to a reduced diameter. Stent **110** can be otherwise identical in structure and fabricated from the same PLLA or absorbable polymer materials as stent **10** described above. Stent **110** can be applied (in the manner of stent **10** described above) to a desired location within a vessel, for example, Vena Cava Inferior, for the purpose of preventing lung emboly. When used in this application, stent **110** can be inserted into Vena Cava with a high degree of precision and functions as a filter.

Stents **10** and **110** offer considerable advantages. In particular, the polymers from which they are formed are highly biocompatible and exhibit good resistance to throm-

bosis and bacteria adhesion. The stents **10** and **110** have a relatively low elastic modulus, moderately low strength, and high ductility. They are therefore durable yet sufficiently flexible that they can be delivered to treatment sites through curved body vessels. The PLLA stents **10** and **110** may exert a gentler radial force against the lumen wall than would the current Elgiloy® stent. The radial force could be made to be higher or lower by utilizing larger or smaller diameter filament in the stent construction.

Although the present invention has been described with reference to preferred embodiments, those skilled in the art will recognize that changes can be made in form and detail without departing from the spirit and scope of the invention.

It will be evident from considerations of the foregoing that the bioabsorbable self-expanding stent **10** may be constructed using a number of methods and materials, in a wide variety of sizes and styles for the greater efficiency and convenience of a user.

Another bioabsorbable stent that may advantageously be used in conjunction with the present invention is disclosed in J. Stinson's U.S. Pat. No. 5,980,564 entitled "Bioabsorbable Implantable Endoprosthesis with Reservoir and Method of Using Same", based on application Ser. No. 08/905,806, filed concurrently herewith, and commonly assigned to the assignee of this application.

A bioabsorbable marker that may advantageously be used in conjunction with the present invention is disclosed in J. Stinson's and Claude Clerc's U.S. Pat. No. 6,340,367 entitled "Radiopaque Markers and Methods of Using Same", based on application Ser. No. 08/905,821, filed concurrently herewith, and commonly assigned to the assignee of this application.

Another bioabsorbable marker that may advantageously be used in conjunction with the present invention is disclosed in J. Stinson's U.S. Pat. No. 6,174,330 entitled "Bioabsorbable Marker Having Radiopaque Constituents and Method of Using Same", based on application Ser. No. 08/904,951, filed concurrently herewith, and commonly assigned to the assignee of this application.

The above described embodiments of the invention are merely descriptive of its principles and are not to be considered limiting. Further modifications of the invention herein disclosed will occur to those skilled in the respective arts and all such modifications are deemed to be within the scope of the invention as defined by the following claims.

What is claimed is:

1. A process for making a prosthesis, including:

providing a plurality of elongate filaments comprising a bioabsorbable material selected from the group consisting of: polydioxanone, polycaprolactone, polygluconate, polylactic acid-polyethylent oxide copolymers, modified cellulose, collagen, poly (hydroxybutyrate), polyanhydride, polyphosphoester, poly(amino acids), poly-L-lactide, poly-D-lactide, polyglycolide, poly(alpha-hydroxy acid) and combinations thereof;

braiding the filaments at a braid angle of from about 120 degrees to about 150 degrees on a first mandrel having a first diameter to form a tubular, radially compressible prosthesis structure;

disposing the prosthesis structure on a second mandrel having a second diameter less than the first diameter; and

while the prosthesis structure is so disposed, annealing the prosthesis structure at a temperature between a glass-transition temperature of the bioabsorbable material and a melting temperature of the bioabsorbable material, to form an annealed prosthesis structure having the annealed diameter D when in a free state, less than an initial diameter of the prosthesis structure before said annealing, the annealed prosthesis structure further being radially compressible to reduced diameters less than the annealed diameter D and radially self-expandable from the reduced diameters.

2. The process of claim **1** wherein:

the bioabsorbable material is selected from the group consisting of poly-L-lactide, poly-D-lactide, polyglycolide, and their combinations.

3. The process of claim **1** wherein:

the first diameter is in the range of 3–30 mm, and the second diameter is in the range of 0.2–10 mm.

4. The process of claim **1** wherein:

said annealing is performed for a time period between about five minutes and about two hours.

5. The process of claim **4** wherein:

said time period is between about 10 minutes and about 20 minutes.

6. The process of claim **1** wherein:

said annealing is performed at an annealing temperature in the range of 60–180 degrees C.

7. The process of claim **6** wherein:

the annealing temperature is in the range of 130–150 degrees C.

8. The process of claim **1** wherein:

said annealing further includes selecting the annealed diameter D based on a predetermined radially outward force to be provided by the annealed prosthesis structure when radially compressed to a predetermined fraction of the annealed diameter D.

9. The process of claim **8** further including:

braiding first and second tubular test structures substantially similar to the unannealed prosthesis structure on the first mandrel;

annealing the first and second tubular test structures on respective first and second test mandrels having different diameters, to form respective first and second annealed test structures having different annealed diameters D_1 and D_2;

loading the first annealed test structure, radially compressed, into a delivery system, deploying the first annealed test structure from the delivery system, then measuring a radially outward force exerted by the deployed first test structure when radially constrained to a predetermined fraction of annealed diameter D_1, thereby to obtain a first radial force value;

loading the second annealed test structure, radially compressed, into the delivery system, deploying the second annealed test structure from the delivery system, then measuring a radially outward force exerted by the deployed second test structure when radially constrained to said predetermined fraction of annealed diameter D_2, thereby to obtain a second radial force value; and

using the first and second annealed diameters D_1 and D_2 and the first and second radial force values to compute and thereby select an annealed diameter D corresponding to the predetermined radially outward force.

10. The process of claim **9** wherein:

said using the first and second annealed diameters and radial force values comprises deriving from said

annealed diameters and the radial force values a linear equation relating annealed diameters to the radial force values corresponding to the radial force exerted by tubular test structures having the annealed diameters when radially compressed to said predetermined fraction of the annealed diameters.

11. The process of claims **10** wherein:

said predetermined fraction of the annealed diameters is one-half, and the linear equation relating the annealed diameters D to the corresponding radial force values RE is:

$$RF=-15D+491 \pm 20.$$

12. For prosthesis structures of the type having elongated bioabsorbable filaments braided on a first mandrel and then annealed on a second mandrel to form annealed tubular structures having annealed diameters when in a free state, radially compressible to reduced diameters less than their annealed diameters, and radially self-expandable from the reduced diameters; a process for selecting an annealed diameter based on a predetermined radially outward force to be provided by a selected annealed tubular structure when radially compressed to a predetermined fraction of the annealed diameter, said process including:

providing first and second prosthesis structures having a first diameter and being of the type formed by braiding bioabsorbable filaments on a first mandrel;

annealing the first prosthesis structure on a first test mandrel to form a first annealed test structure having an annealed diameter D_1 less than the first diameter;

annealing the second prosthesis structure on a second test mandrel different in diameter from the first test mandrel, to form a second annealed test structure having an annealed diameter D_2 less than the first diameter and different from annealed diameter D_1;

radially compressing the first annealed test structure to a reduced diameter D_3 less than diameters D_1 and D_2, allowing the first test structure to radially self-expand to a predetermined fraction of annealed diameter D_1, then measuring a radially outward force exerted by the first test structure when at the predetermined fraction of annealed diameter D_1 to obtain a first radial force value;

radially compressing the second annealed test structure to said diameter D_3, allowing the second test structure to self-expand to said predetermined fraction of annealed diameter D_2, then measuring a radially outward force exerted by the second test structure when at the predetermined fraction of annealed diameter D_2 to obtain a second radial force value; and

using the first and second annealed diameters D_1 and D_2 and the first and second radial force values to compute and thereby select an annealed diameter D corresponding to a predetermined radially outward force.

13. The process of claim **12** wherein:

said using the first and second annealed diameters and radial force values comprises deriving from said annealed diameters and the radial force values a linear equation relating annealed diameters to the radial force values corresponding to the radial force exerted by tubular test structures having the annealed diameters when radially compressed to said predetermined fraction of the annealed diameters.

14. The process of claim **13** wherein:

the predetermined fraction of the annealed diameters is one-half, and the linear equation relating and annealed diameters D to the corresponding radial force values RF is:

$$RF=-15D+491 \pm 20.$$

15. A process for making a prosthesis, including:

braiding a plurality of elongate bioabsorable filaments on a first mandrel having a first diameter to form a tubular, radially compressible prosthesis structure;

selecting a second mandrel having a second diameter less than the first diameter for annealing the prosthesis structure at an annealed diameter D based on a predetermined radially outward force to be exerted by the annealed prosthesis structure when radially compressed to a predetermined fraction of the annealed diameter D; and

while the prosthesis structure is so disposed, annealing the prosthesis structure at a temperature between a glass transition temperature of the bioabsorable material and a melting temperature of the bioabsorable material, to form an annealed prosthesis structure having the annealed diameter D when in a free state less than an initial diameter of the prosthesis structure before said annealing, the annealed prosthesis structure further being radially compressible to reduced diameters less than the annealed diameter D and radially self-expandable from the reduced diameters.

16. The process of claim **15** wherein:

the elongate bioabsorbable filaments comprise a material selected from the group consisting of: polydioxanone, polycaprolactone, polygluconate, polylactic acid-polyethylene oxide copolymers, modified cellulose, collagen, poly(hydroxybutyrate), polyanhydride, polyphosphoester, poly(amino acids), poly-L-lactide, poly-D-lactide, polyglycolide, poly(alpha-hydroxy acid) and combinations thereof.

17. The process of claim **15** wherein:

said annealing is performed at annealing temperatures within the range of 60 degrees C. to 180 degrees C.

18. The process of claim **15** wherein:

said annealing is performed for a time period between about five minutes and about two hours.

19. A process for making a prosthesis, including:

providing a plurality of elongate filaments comprising a bioabsorbable material selected from the group consisting of: polydioxanone, polycaprolactone, polygluconate, polylactic acid-polyethylene oxide copolymers, modified cellulose, collagen, poly (hydroxybutyrate), polyanhydride, polyphosphoester, poly(amino acids), poly-L-lactide, poly-D-lactide, polyglycolide, poly(alpha-hydroxy acid) and combinations thereof;

braiding the filaments on a first mandrel having a first diameter to form a tubular, radially compressible prosthesis structure;

disposing the prosthesis structure on a second mandrel having a second diameter less than the first diameter;

selecting an annealed diameter D based on a predetermined radially outward force to be provided by the annealed prosthesis structure when radially compressed to a predetermined fraction of the annealed diameter D; and

while the prosthesis structure is so disposed, annealing the prosthesis structure at a temperature between a glass-transition temperature of the bioabsorbable material and a melting temperature of the bioabsorbable material, to form an annealed prosthesis structure having the annealed diameter D when in a free state, less than an initial diameter of the prosthesis structure

before said annealing, the annealed prosthesis structure further being radially compressible to reduced diameters less than the annealed diameter D and radially self-expandable from the reduced diameters.

20. The process of claim **19** wherein:

the bioabsorbable material is selected from the group consisting of poly-L-lactide, poly-D-lactide, polyglycolide, and their combinations.

21. The process of claim **19** wherein:

the first diameter is in the range of 3–30 mm, and the second diameter is in the range of 0.2–10 mm.

22. The process of claim **19** wherein:

said braiding comprises winding the filaments to form a braid angle of from about 120 degrees to about 150 degrees.

23. The process of claim **19** wherein:

said annealing is performed for a time period between about five minutes and about two hours.

24. The process of claim **19** wherein:

said annealing is performed at an annealing temperature in the range of 60–180 degrees C.

25. The process of claim **19** further including:

braiding first and second tubular test structures substantially similar to the unannealed prosthesis structure on the first mandrel;

annealing the first and second tubular test structures on respective first and second test mandrels having different diameters, to form respective first and second annealed test structures having different annealed diameters D_1 and D_2;

loading the first annealed test structure, radially compressed, into a delivery system, deploying the first annealed test structure from the delivery system, then measuring a radially outward force exerted by the deployed first test structure when radially constrained to a predetennined fraction of annealed diameter D_1, thereby to obtain a first radial force value;

loading the second annealed test structure, radially compressed, into the delivery system, deploying the second annealed test structure from the delivery system, then measuring a radially outward force exerted by the deployed second test structure when radially constrained to said predetermined fraction of annealed diameter D_2, thereby to obtain a second radial force value; and

using the first and second annealed diameters D_1 and D_2 and the first and second radial force values to compute and thereby select an annealed diameter D corresponding to the predetermined radially outward force.

26. The process of claim **25** wherein:

said using the first and second annealed diameters and radial force values comprises deriving from said annealed diameters and the radial force values a linear equation relating annealed diameters to the radial force values corresponding to the radial force exerted by tubular test structures having the annealed diameters when radially compressed to said predetermined fraction of the annealed diameters.

27. The process of claim **26** wherein:

said predetermined fraction of the annealed diameters is one-half, and the linear equation relating the annealed diameters D to the corresponding radial force values RF is:

$$RF=-15D+491 \pm 20.$$

* * * * *

US006245103B1

(12) **United States Patent**
Stinson

(10) **Patent No.: US 6,245,103 B1**
(45) **Date of Patent: *Jun. 12, 2001**

(54) **BIOABSORBABLE SELF-EXPANDING STENT**

(75) Inventor: **Jonathan S. Stinson**, Plymouth, MN (US)

(73) Assignee: **Schneider (USA) Inc**, Plymouth, MN (US)

(*) Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **08/904,467**

(22) Filed: **Aug. 1, 1997**

(51) **Int. Cl.**[7] **A61F 2/06**
(52) **U.S. Cl.** **623/1.22**; 623/1.38; 606/200
(58) **Field of Search** 623/1, 12, 1.22, 623/1.38–1.49; 427/2.1–2.31

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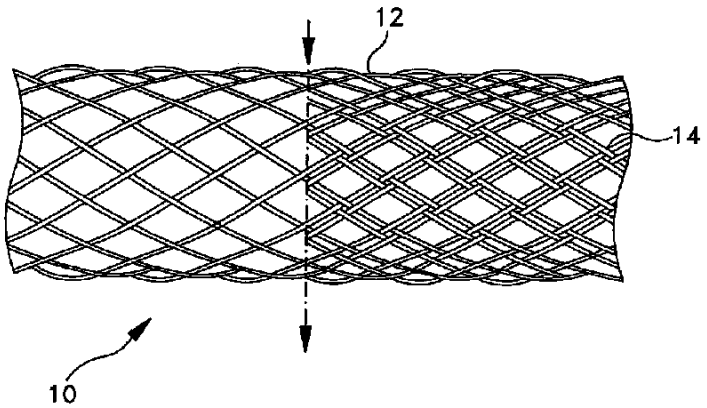
(57) **ABSTRACT**

A self-expanding stent formed from helically wound and braided filaments of bioabsorbable polymers such as PLA, PLLA, PDLA, and PGA.

39 Claims, 16 Drawing Sheets



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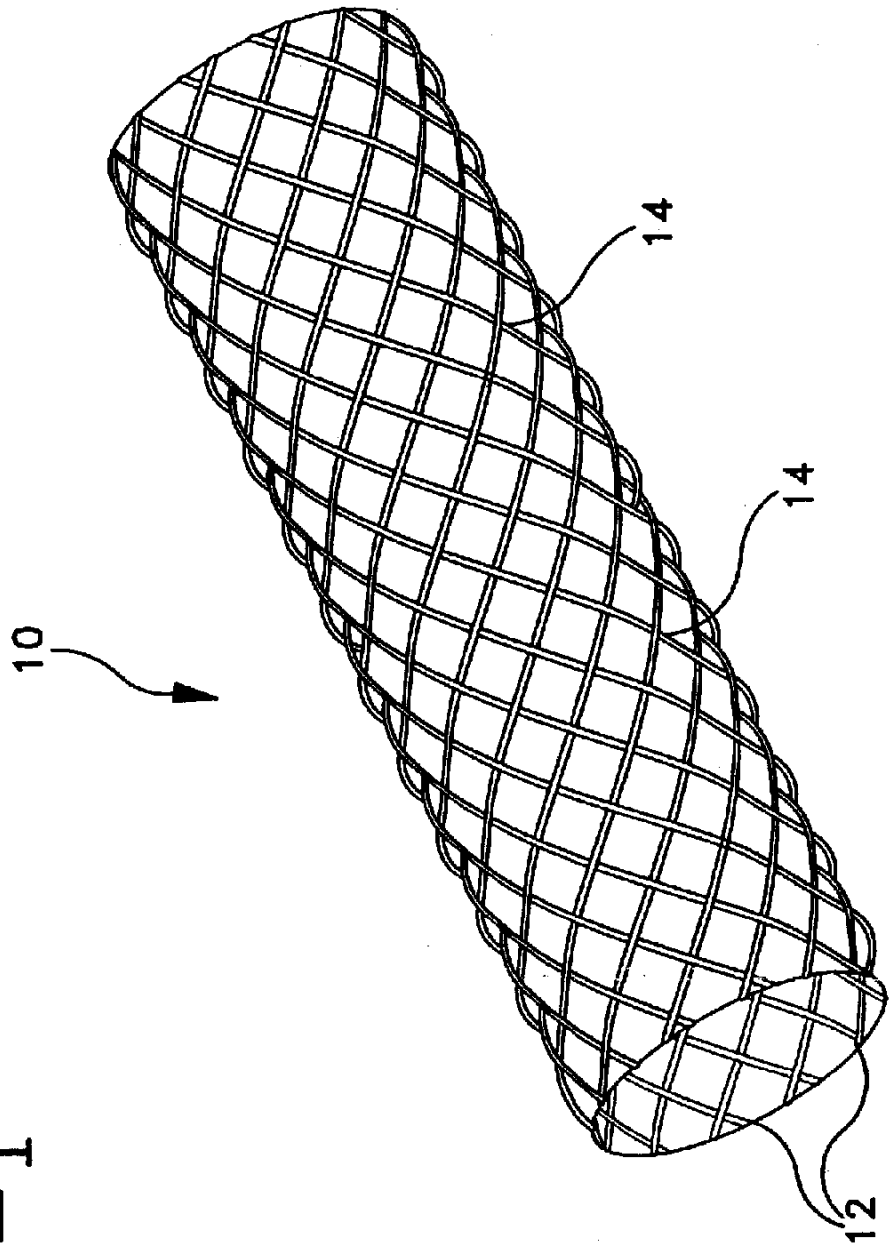


FIG-1

FIG-2

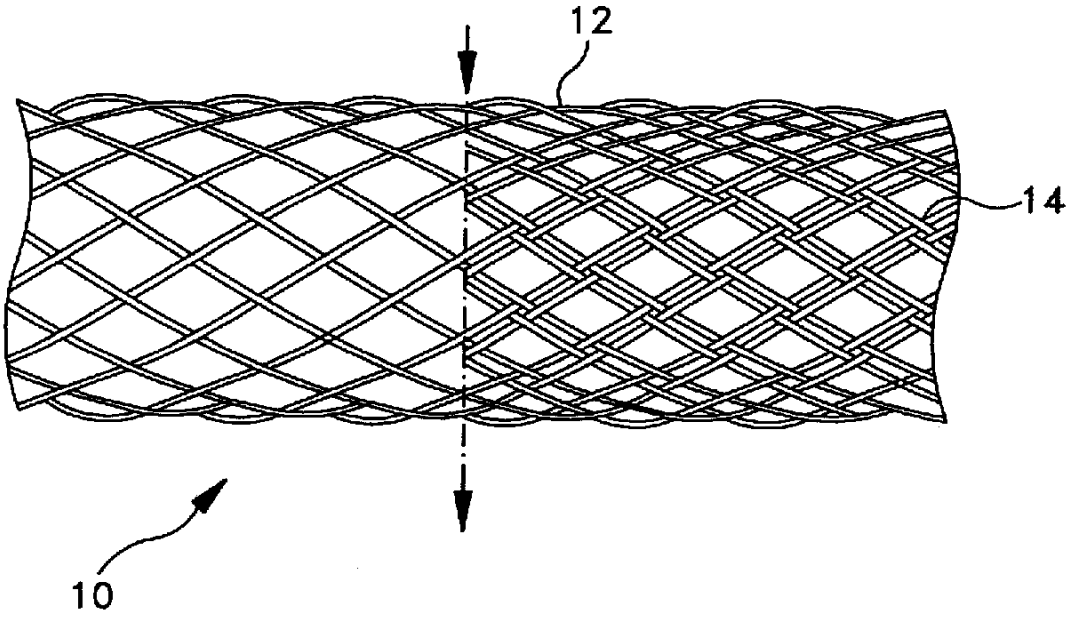
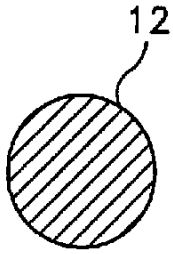


FIG-3



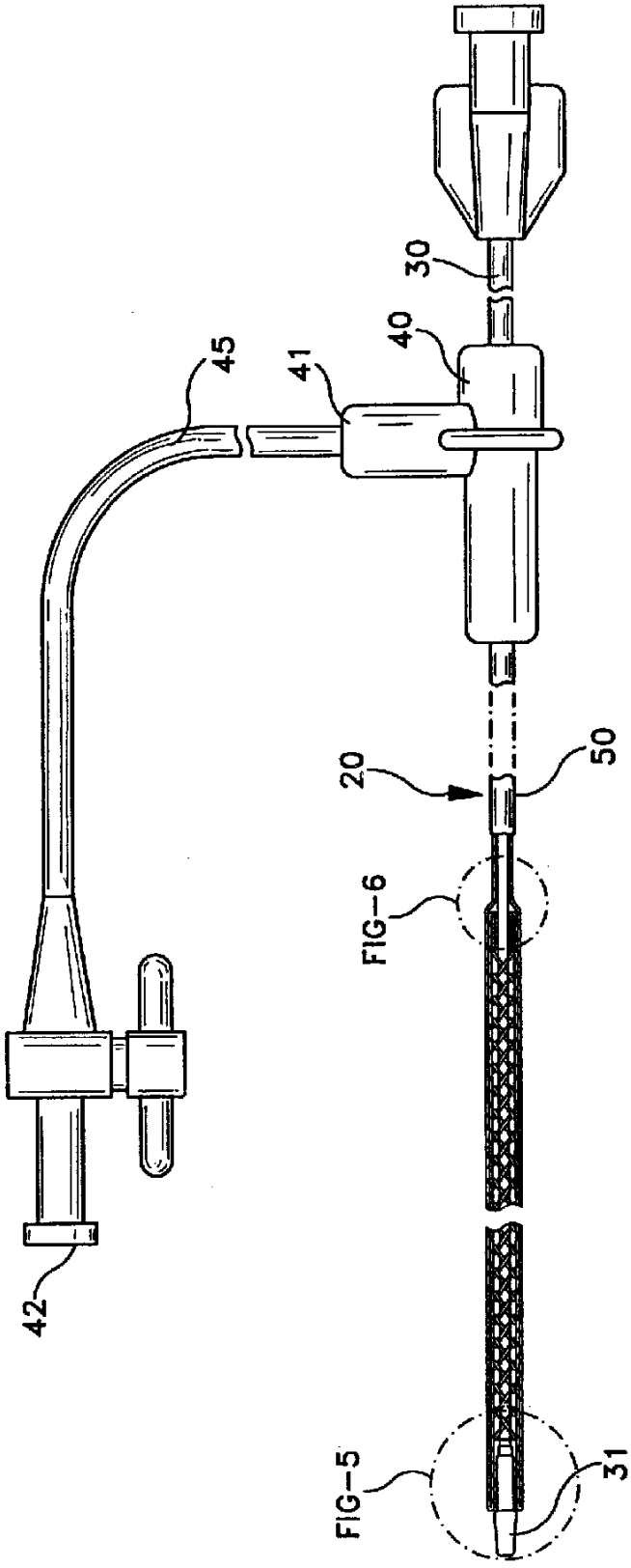
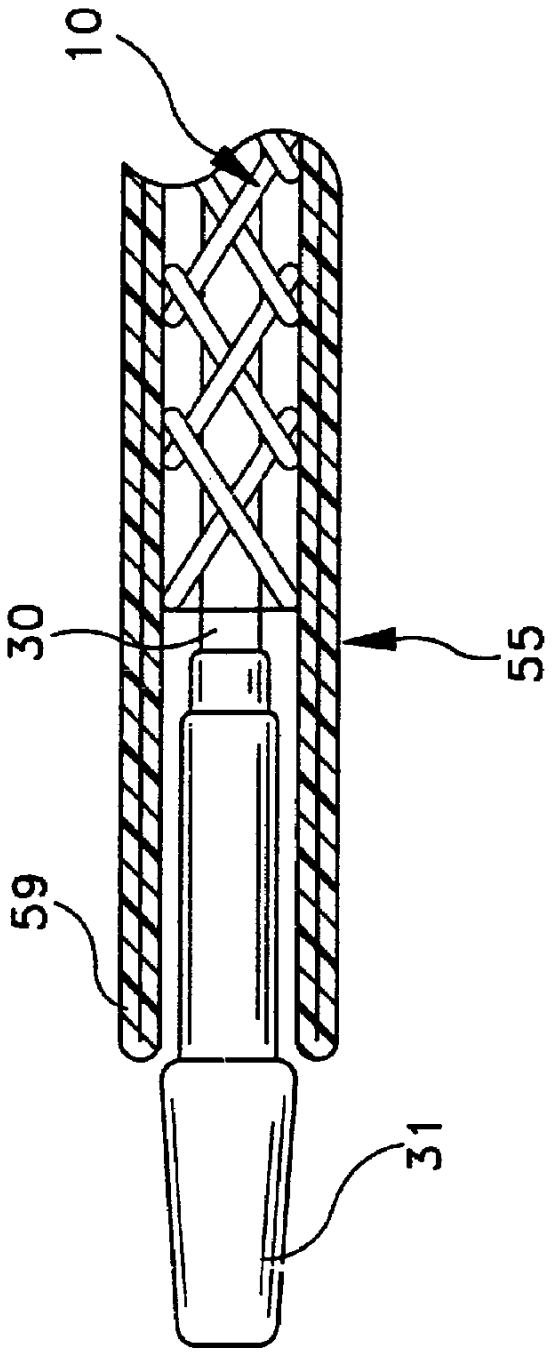


FIG-4



FIG—5

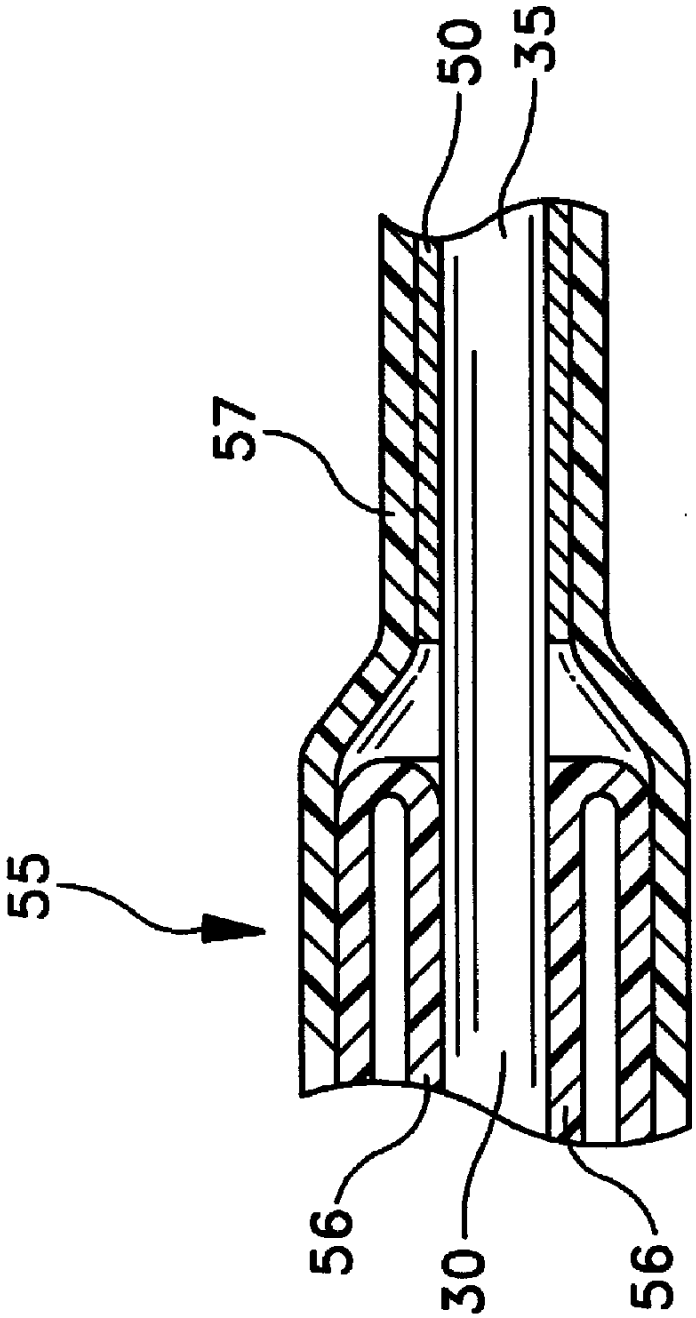
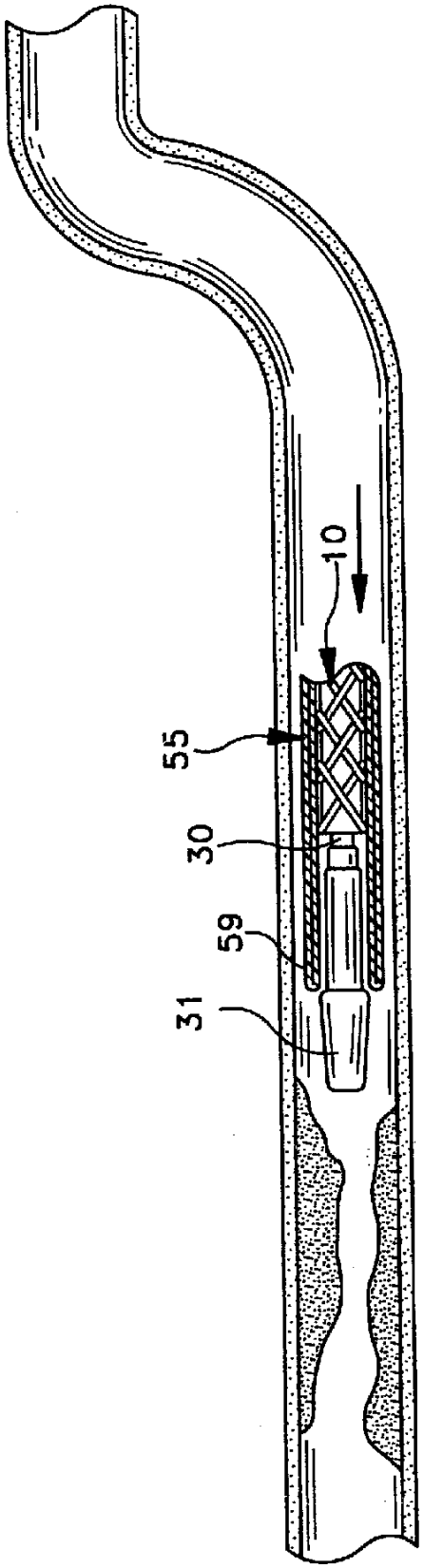


FIG-6



FIG—7

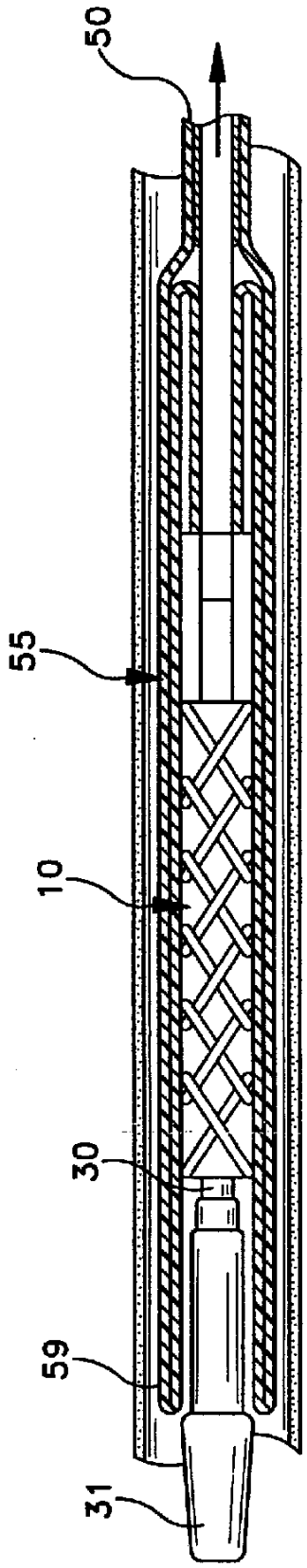


FIG-8

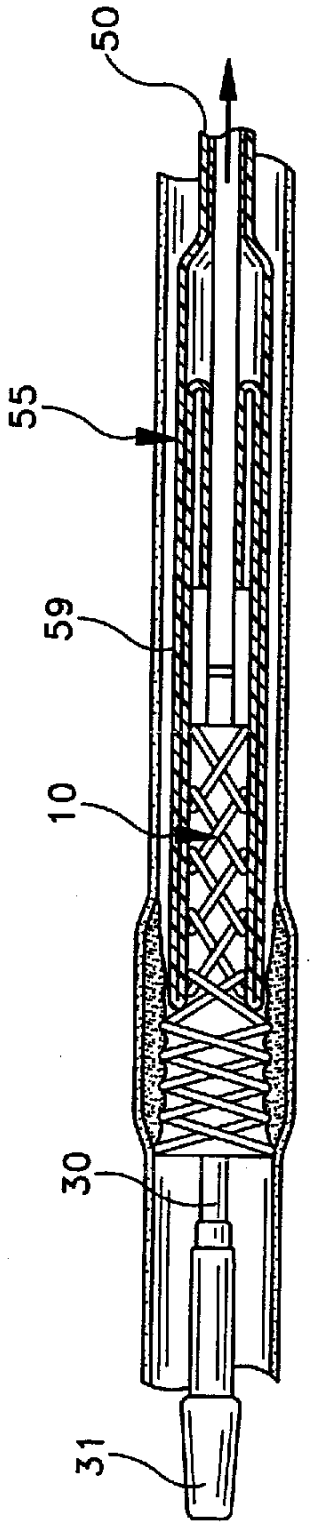


FIG-9

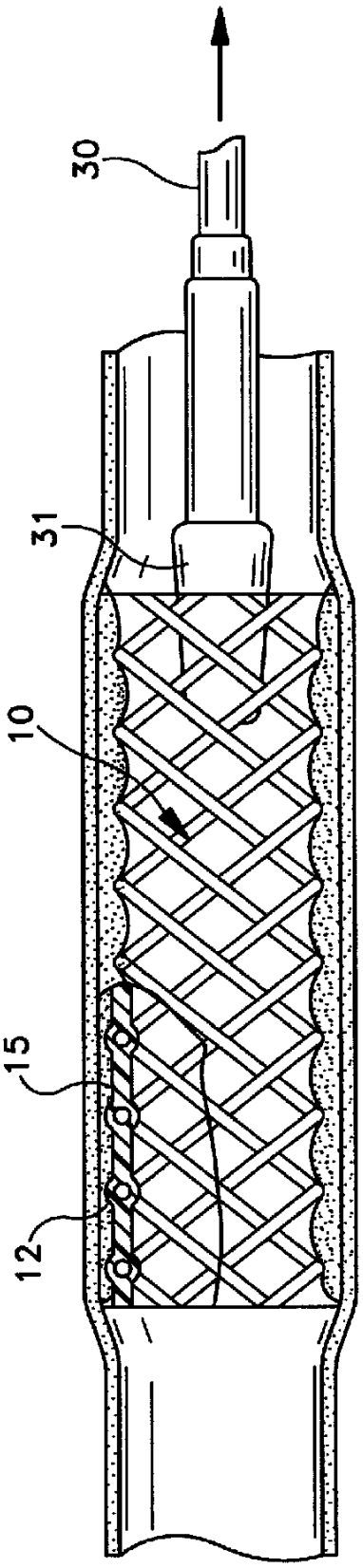
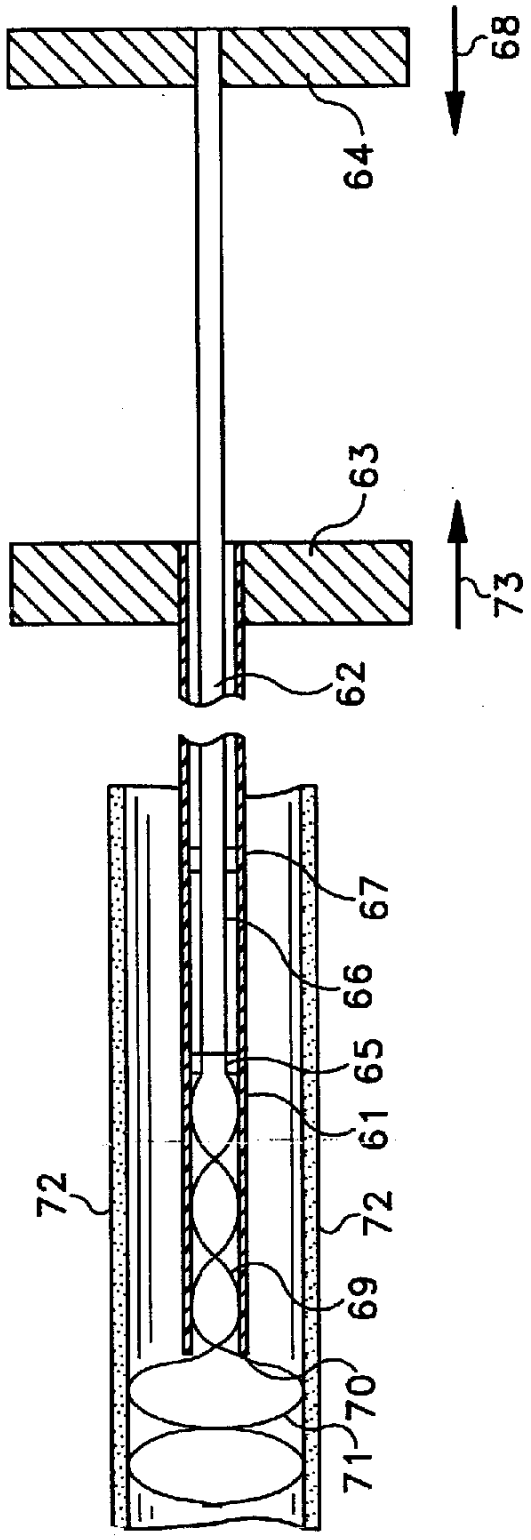


FIG-10



FIG–11

FIG-12

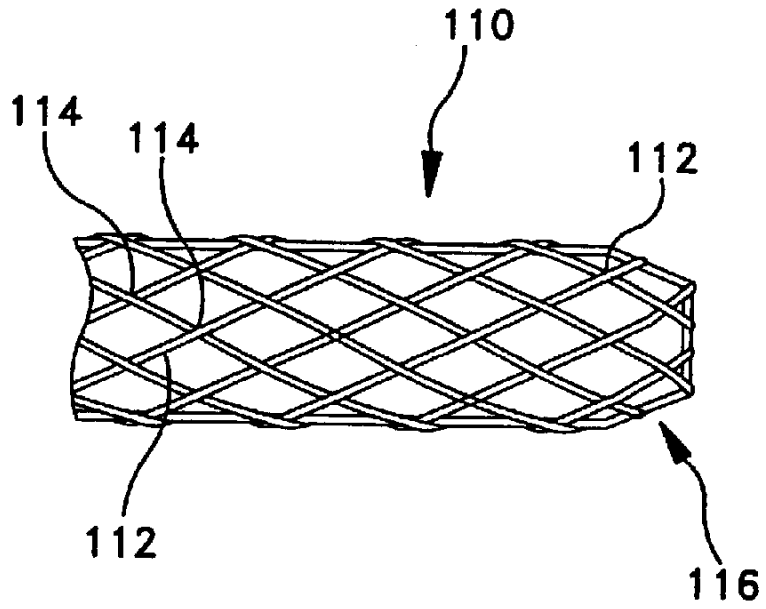


FIG-13

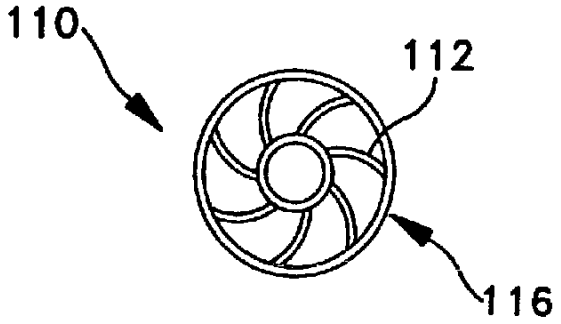
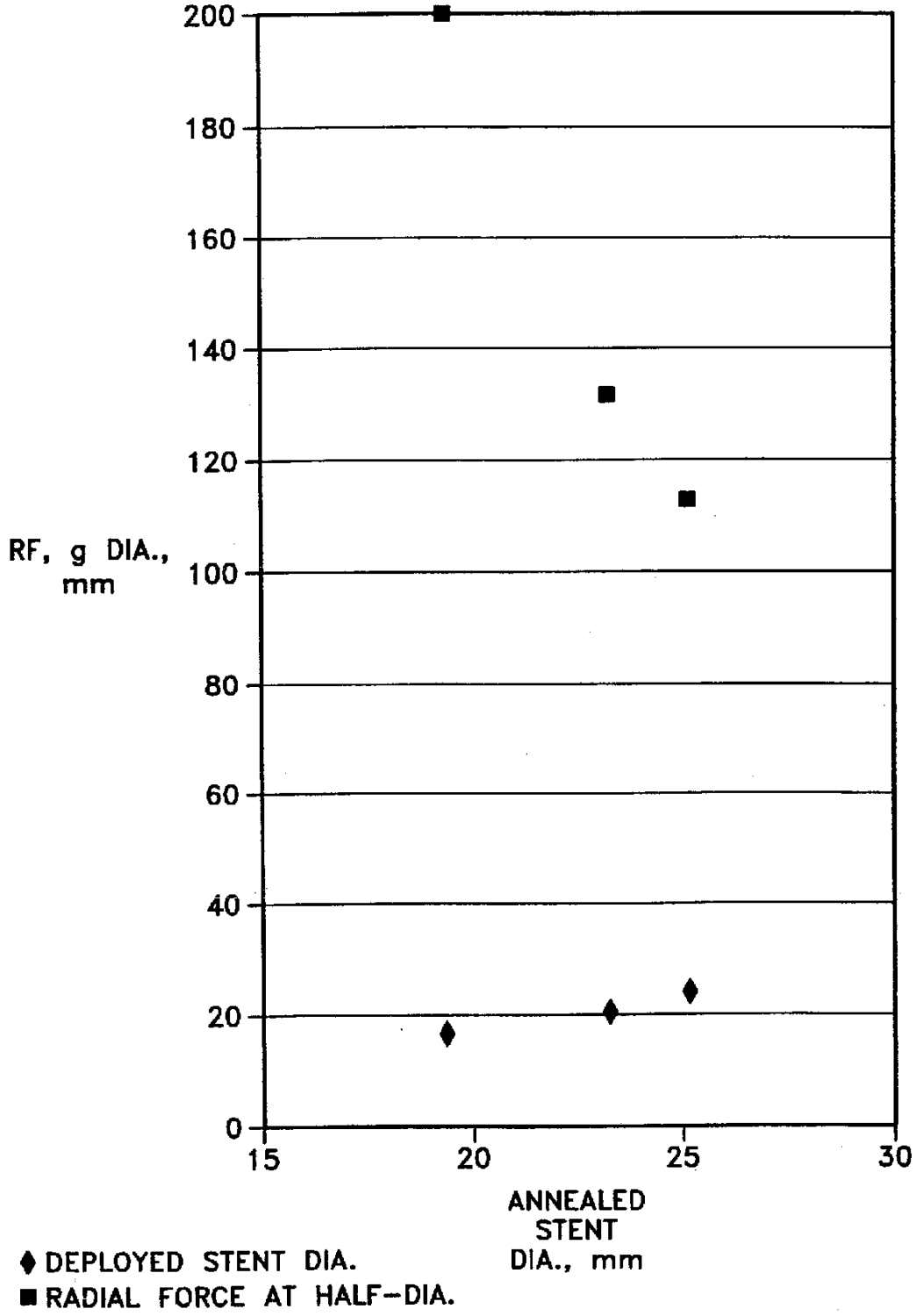


FIG-14


200
180
160
140
120
100
80
60
40
20
0
RF, g DIA., mm
15
20
25
30
ANNEALED STENT DIA., mm
♦ DEPLOYED STENT DIA.
■ RADIAL FORCE AT HALF-DIA.

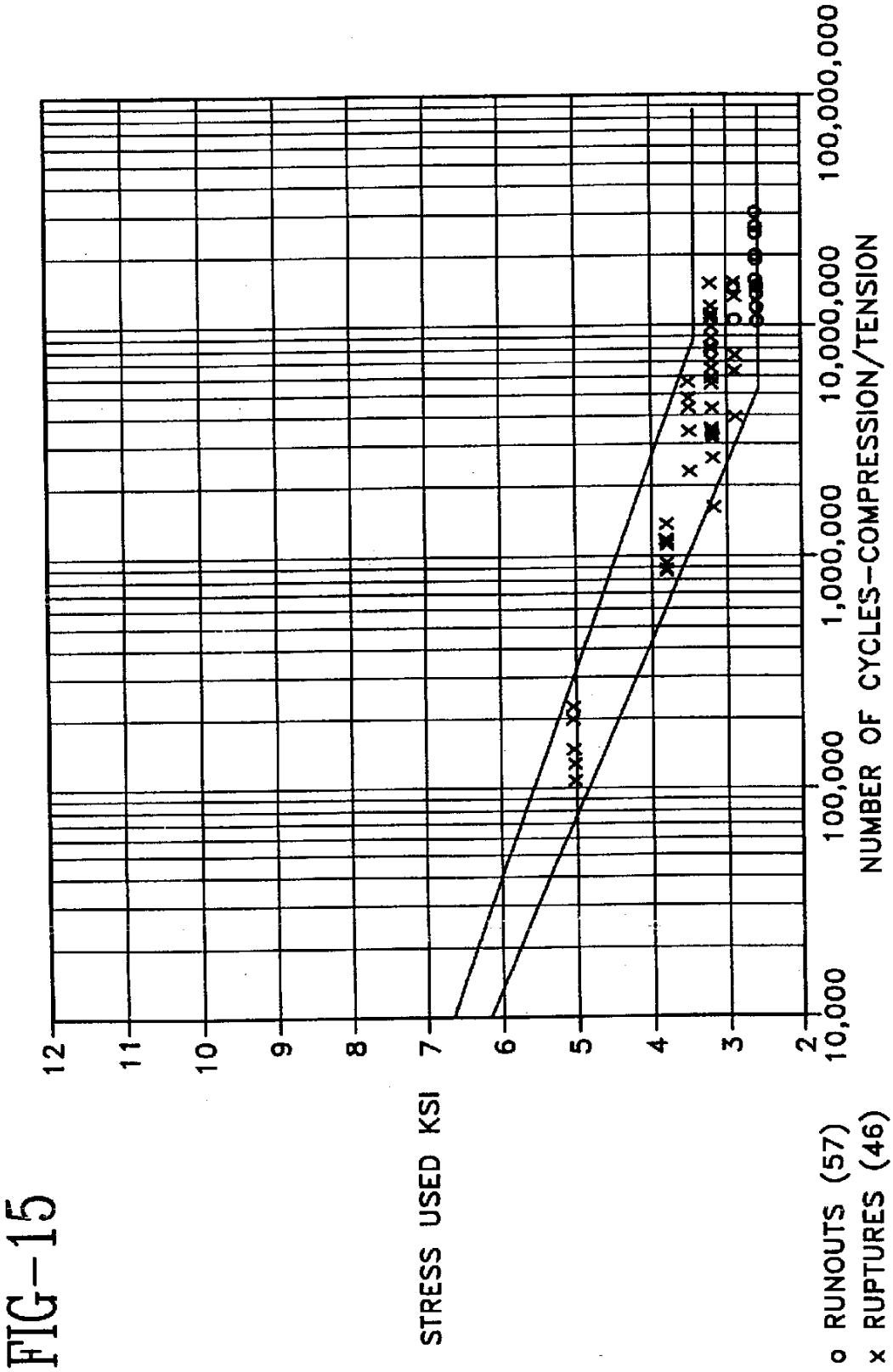
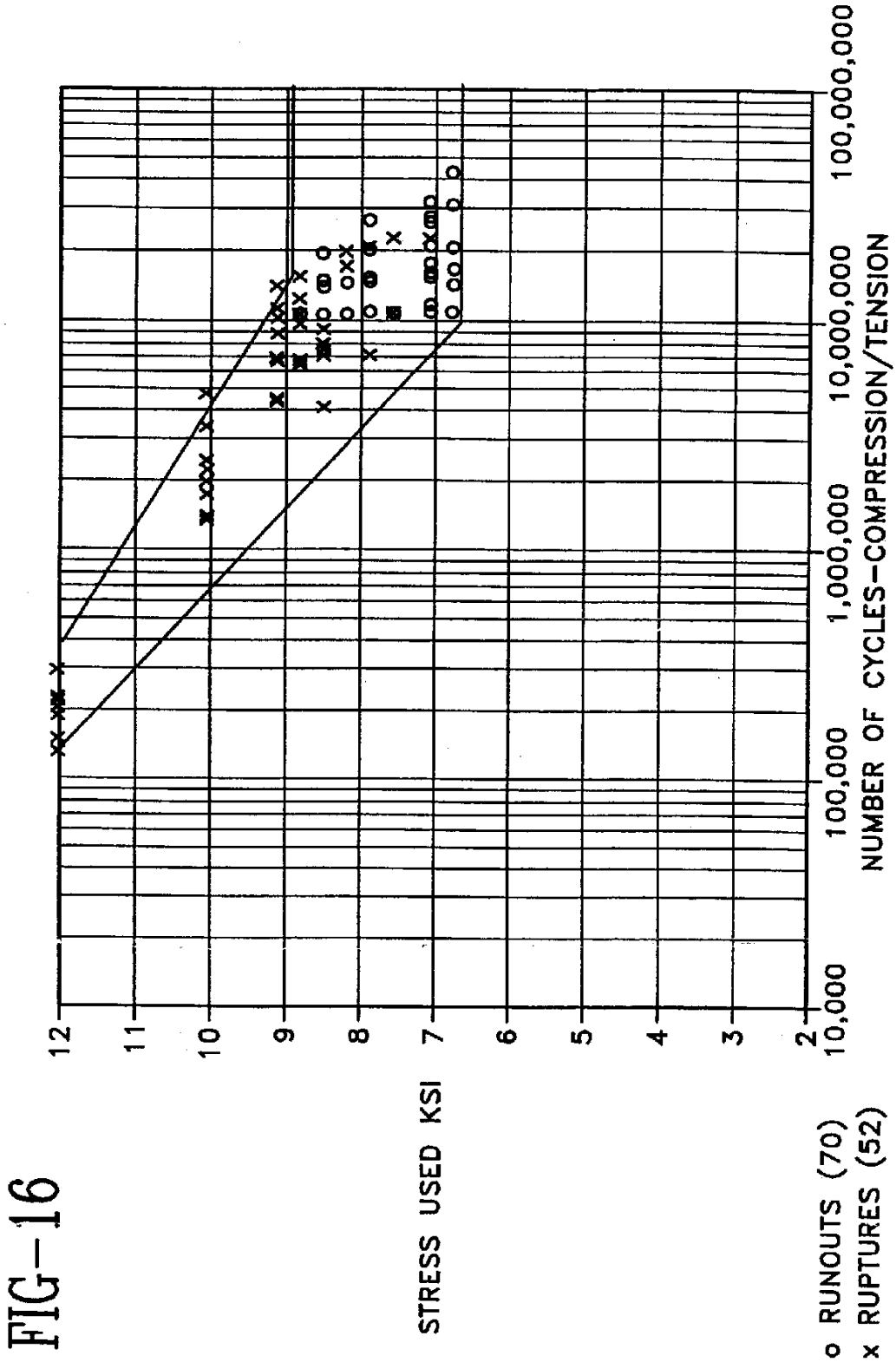

12
11
10
9
8
7
6
5
4
3
2
STRESS USED KSI
10,000
100,000
1,000,000
10,000,000
100,000,000
NUMBER OF CYCLES—COMPRESSION/TENSION
o RUNOUTS (57)
x RUPTURES (46)

FIG-15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7
6
5
4
3
2
STRESS USED KSI
10,000
100,000
1,000,000
10,000,000
100,000,000
NUMBER OF CYCLES-COMPRESSION/TENSION
o RUNOUTS (70)
x RUPTURES (52)

FIG-16

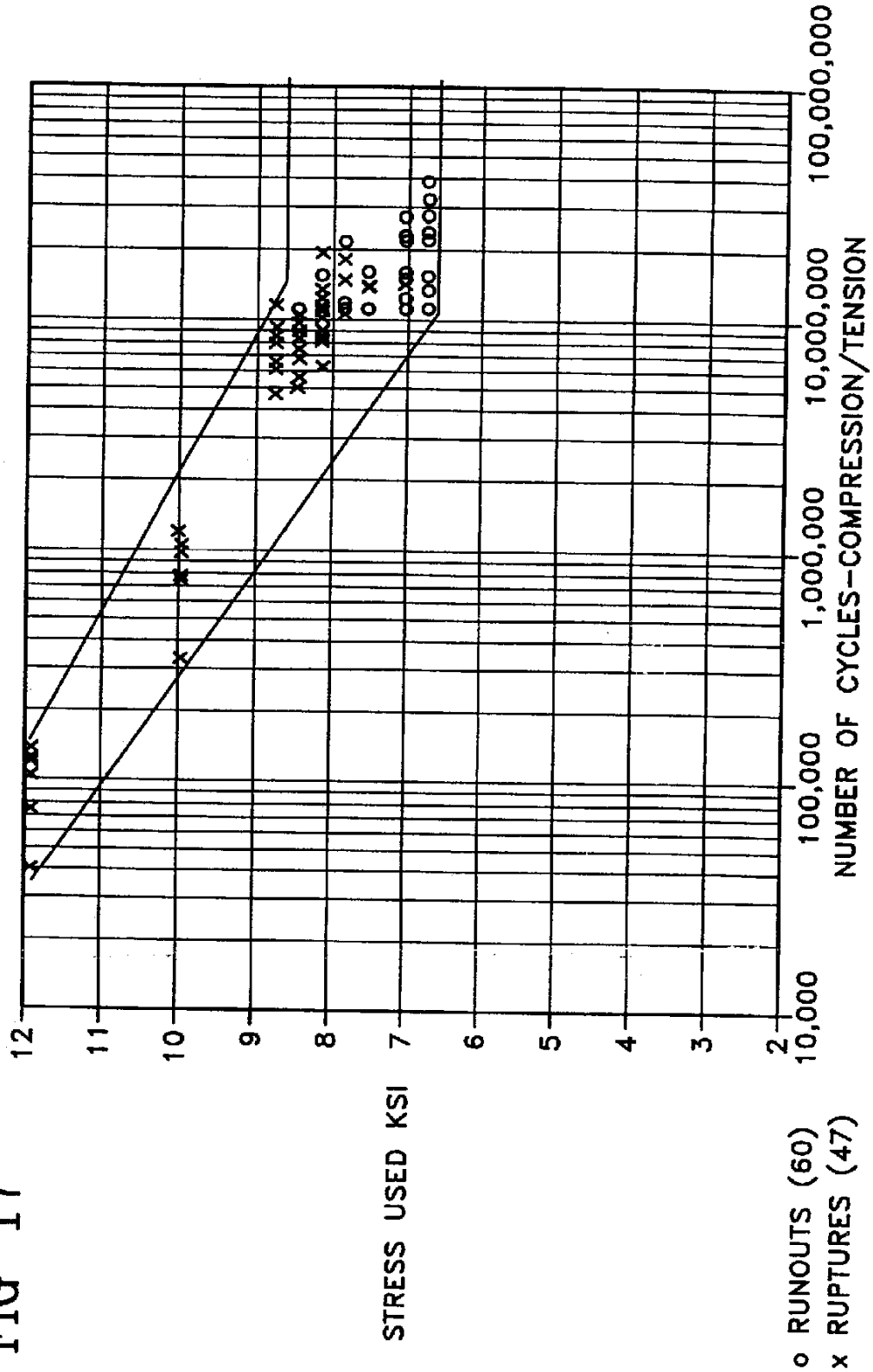
STRESS USED KSI
12
11
10
9
8
7
6
5
4
3
2
10,000
100,000
1,000,000
10,000,000
100,000,000
NUMBER OF CYCLES-COMPRESSION/TENSION
o RUNOUTS (60)
x RUPTURES (47)

FIG-17

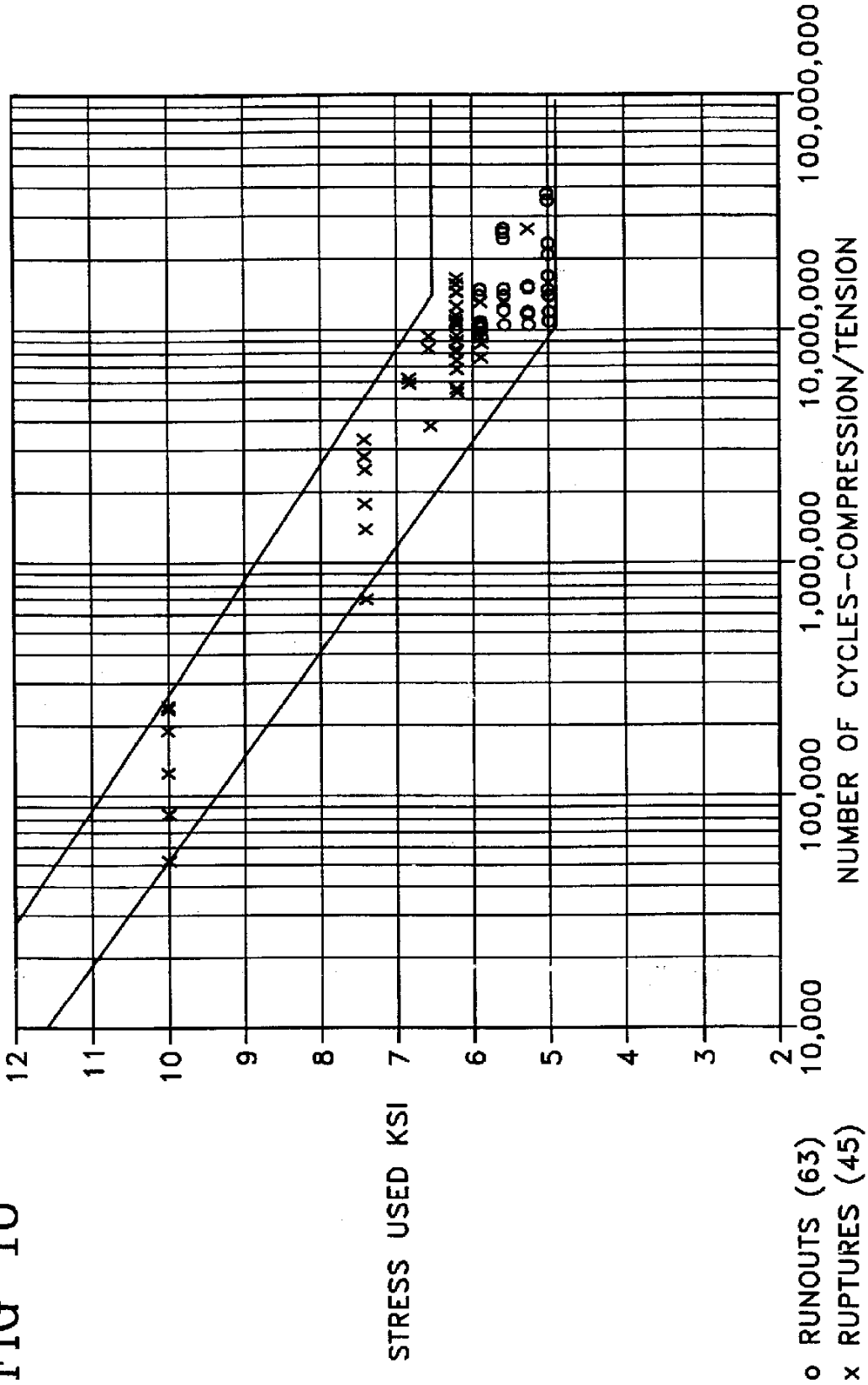
12
11
10
9
8
7
6
5
4
3
2
10,000
100,000
1,000,000
10,000,000
100,000,000
NUMBER OF CYCLES-COMPRESSION/TENSION
STRESS USED KSI
o RUNOUTS (63)
x RUPTURES (45)

FIG-18

BIOABSORBABLE SELF-EXPANDING STENT

BACKGROUND OF THE INVENTION

The present invention relates generally to implantable, radially expandable medical prostheses which are frequently referred to as stents. In particular, the present invention is a bioabsorbable self-expanding stent.

Self-expanding medical prostheses frequently referred to as stents are well known and commercially available. They are, for example, disclosed generally in the Wallsten U.S. Pat. No. 4,655,771, the Walisten et al. U.S. Pat. No. 5,061, 275 and in Hachtmann et al., U.S. Pat. No. 5,645,559. Devices are used within body vessels of humans for a variety of medical applications. Examples include intravascular stents for treating stenoses, stents for maintaining openings in the urinary, biliary, tracheobronchial, esophageal, and renal tracts, and vena cava filters.

A delivery device which retains the stent in its compressed state is used to deliver the stent to a treatment site through vessels in the body. The flexible nature and reduced radius of the compressed stent enables it to be delivered through relatively small and curved vessels. In percutaneous transluminal angioplasty, an implantable endoprosthesis is introduced through a small percutaneous puncture site, airway, or port and is passed through various body vessels to the treatment site. After the stent is positioned at the treatment site, the delivery device is actuated to release the stent, thereby allowing the stent to self-expand within the body vessel. The delivery device is then detached from the stent and removed from the patient. The stent remains in the vessel at the treatment site as an implant

Stents must exhibit a relatively high degree of biocompatibility since they are implanted in the body. An endoprosthesis may be delivered into a body lumen on or within a surgical delivery system such as delivery devices shown in U.S. Pat. Nos. 4,954,126 and 5,026,377. Preferred delivery devices for the present invention include U.S. Pat. Nos. 4,954,126; 5,026,377. Suitable materials for use with such delivery devices are described in U.S. patent application Ser. No. 08/833,639, filed Apr. 8, 1997.

Commonly used materials for known stent filaments include Elgiloy® and Phynox® metal spring alloys. Other metallic materials than can be used for self-expanding stent filaments are 316 stainless steel, MP35N alloy, and superelastic Nitinol nickel-titanium. Another self-expanding stent, available from Schneider (USA) Inc. of Minneapolis, Minn., has a radiopaque clad composite structure such as shown in U.S. Pat. No. 5,630,840 to Mayer. Self-expanding stents can be made of a Titanium Alloy as described in United States patent application Ser. No. 08/598,751, filed Feb. 8, 1996.

The strength and modulus of elasticity of the filaments forming the stents are also important characteristics. Elgiloy®, Phynox®, MP35N and stainless steel are all high strength and high modulus metals. Nitinol has relatively low strength and modulus.

The implantation of an intraluminal stent will preferably cause a generally reduced amount of acute and chronic trauma to the luminal wall while performing its function. A stent that applies a gentle radial force against the wall and that is compliant and flexible with lumen movements is preferred for use in diseased, weakened, or brittle lumens. The stent will preferably be capable of withstanding radially occlusive pressure from tumors, plaque, and luminal recoil and remodeling.

There remains a continuing need for self-expanding stents with particular characteristics for use in various medical indications. Stents are needed for implantation in an ever growing list of vessels in the body. Different physiological environments are encountered and it is recognized that there is no universally acceptable set of stent characteristics.

A need exists for a stent which has self expanding characteristics, but which is bioabsorbable. A surgical implant such as a stent endoprosthesis must be made of a non-toxic, biocompatible material in order to minimize the foreign-body response of the host tissue. The implant must also have sufficient structural strength, biostability, size, and durability to withstand the conditions and confinement in a body lumen.

All documents cited herein, including the foregoing, are incorporated herein by reference in their entireties for all purposes.

SUMMARY OF THE INVENTION

The present invention is an improved implantable medical device comprised of a tubular, radially compressible, axially flexible and radially self-expandable structure including elongate filaments formed in a braid-like configuration. The filaments consist of a bioabsorbable polymer which exhibits a relatively high degree of biocompatibility.

Briefly, self-expanding stents of the present invention are formed from a number of resilient filaments which are helically wound and interwoven in a braided configuration. The stents assume a substantially tubular form in their unloaded or expanded state when they are not subjected to external forces. When subjected to inwardly directed radial forces the stents are forced into a reduced-radius and extended-length loaded or compressed state. The stents are generally characterized by a longitudinal shortening upon radial expansion.

In one preferred embodiment, the device is a stent which substantially consists of a plurality of elongate polylactide bioabsorbable polymer filaments, helically wound and interwoven in a braided configuration to form a tube. Bioabsorbable implantable endoprostheses such as stents, stent-grafts, grafts, filters, occlusive devices, and valves may be made of poly(alpha-hydroxy acid) such as poly-L-lactide (PLLA), poly-D-lactide (PDLA), polyglycolide (PGA), polydioxanone, polycaprolactone, polygluconate, polylactic acid-polyethylene oxide copolymers, modified cellulose, collagen, poly(hydroxybutyrate), polyanhydride, polyphosphoester, poly(amino acids), or related copolymers materials, each of which have a characteristic degradation rate in the body. For example, PGA and polydioxanone are relatively fast-bioabsorbing materials (weeks to months) and PLA and polycaprolactone are a relatively slow-bioabsorbing material (months to years).

A stent constructed of a bioabsorbable polymer provides certain advantages relative to metal stents such as natural decomposition into non-toxic chemical species over a period of time. Also, bioabsorbable polymeric stents may be manufactured at relatively low manufacturing costs since vacuum heat treatment and chemical cleaning commonly used in metal stent manufacturing are not required.

The present invention includes a method of designing and manufacturing an improved braided bioabsorbable stent which is different from practices used to make braided metal wire stents. The method involves selecting a specific bioabsorbable polymer based on a desired stent functional absorption time and stent radial force. The stent functional absorption time is the time period within which the stent

retains at least 80% of its original radial strength. The stent is made by first selecting a braid design from the invention and making two different annealed stents. Radial force and dimensional test results from the two stents are used to develop a nearly linear mathematical equation to determine the parameters to meet the design goals. This method advantageously limits costly and time consuming trial and error to arrive at the optimum design.

Bioabsorbable polymer stents are radiolucent and the mechanical properties of the polymers are generally lower than structural metal alloys. Bioabsorbable stents may require radiopaque markers and may have a larger profile on a delivery catheter and in a body lumen to compensate for the lower material properties.

Bioabsorbable PLLA and PGA material are degraded in vivo through hydrolytic chain scission to lactic acid and glycolic acid, respectively, which in turn is converted to CO_2 and then eliminated from the body by respiration. Heterogeneous degradation of semicrystalline polymers occurs due to the fact that such materials have amorphous and crystalline regions. Degradation occurs more rapidly at amorphous regions than at crystalline regions. This results in the product decreasing in strength faster than it decreases in mass. Totally amorphous, cross-linked polyesters show a more linear decrease in strength with mass over time as compared to a material with crystalline and amorphous regions. Degradation time may be affected by variations in chemical composition and polymer chain structures, and material processing.

PLA monofilaments may be produced by a process involving seven general steps as summarized herein. First, a polymer formed of poly-L-lactic acid is brought to an elevated temperature above the melting point, preferably 210°–230° C. Second, the material is then extruded at the elevated temperature into a continuous fiber, by a conventional process, at a rate about of three to four feet per minute. Third, the continuous fiber is then cooled to cause nucleation. The cooling is preferably performed by passing the fiber through a nucleation bath of water. Fourth, the material then passes through a first puller, which runs at about the same speed as the extruder, and places the material under slight tension. Fifth, the fiber is then heated to a temperature between about 60° C. and about 90° C. (preferably 70° C.) as it passes through a heated oven. To perform annealing, the oven can be designed to be quite long and heated near the end, so that the orientation and annealing take place in the same oven. Alternatively, a separate oven can be placed directly after the orientation oven. The annealing step heats the fibers to a range of about 65° C. to about 90° C., preferably closer to 90° C. Sixth, while being heated in the orientation oven and the annealing oven, the fiber is drawn between the first puller located before the orientation oven and a second puller located after the annealing oven (if a separate oven). The material is drawn at a draw ratio of between about 5 to about 9, preferably between about 6 and about 8. Draw ratio describes the extension in length resulting from polymer extrusion or drawing. Quantitatively, the drawing ratio is a unitless value equal to the extruded or drawn length divided by the original length. Maintaining tension through the annealing step prevents shrinkage in later use. The second puller, located at the exit of the oven, runs at an increased speed necessary to provide the desired draw ratio. As the fiber exits the oven and passes through the second puller the tension is immediately released before the material cools. Seventh, finally, the fiber is collected onto spools of desired lengths.

Strength of the filaments generally increases with draw ratio and with lower draw temperatures. A draw ratio of between 5 and 9 is preferred. PIA is generally amorphous because of the material's slow crystallization kinetics. Very slow cooling after drawing of the filament or use of a nucleating agent will cause crystallization. However, the material may be annealed at temperatures above about 60° C. to cause crystallization, and generally, the strength decreases slightly and the modulus increases. Annealing is preferably performed after drawing to release residual stresses and to homogenize the surface to center variations in structure. Annealing will preferably be performed at a temperature of between about 60° C. and 150° C. for a period of time between about 5 and 120 minutes. Reference is made to *Enhancement of the Mechanical properties of polylactides by solid-state extrusion,* W. Weiler and S. Gogolewski, Biomaterials 1996, Vol 17 No. 5, pp. 529–535; and *Deformation Characteristics of a Bioabsorbable Intravascular Stent*, Investigative Radiology, Dec. 1992, C. Mauli, Agrawal, Ph.D., P.E., H. G. Clark, Ph.D., pp. 1020–1024. It is generally preferred in accordance with this invention that the annealed bioabsorbable filament has a substantially homogeneous cross-section, in other words, that it has a substantially solid cross-section without substantial variations between the center and the surface of the filament.

Mechanical properties generally increase with increasing molecular weight. For instance, the strength and modulus of PLA generally increases with increasing molecular weight. Degradation time generally decreases with decreasing initial molecular weight (i.e., a stent made of a low molecular weight polymer would be bioabsorbed before a stent made of a high molecular weight polymer). Low molecular weight PLA is generally more susceptible to thermo-oxidative degradation than high molecular weight grades, so an optimum molecular weight range should be selected to balance properties, degradation time, and stability. The molecular weight and mechanical properties of the material generally decreases as degradation progresses. PLA generally has a degradation time greater than 1 year. Ethylene oxide sterilization process (EtO) is a preferred method of sterilization. PLA has a glass transition temperature of about 60° C., so care must be taken not to store products in environments where high temperature exposure may result in dimensional distortion.

PLA, PLLA, PDLA and PGA include tensile strengths of from about 40 thousands of pounds per square inch (ksi) to about 120 ksi; a tensile strength of 80 ksi is typical; and a preferred tensile strength of from about 60 ksi to about 120 ksi. Polydioxanone, polycaprolactone, and polygluconate include tensile strengths of from about 15 ksi to about 60 ksi; a tensile strength of 35 ksi is typical; and a preferred tensile strength of from about 25 ksi to about 45 ksi.

PLA, PLLA, PDLA and PGA include tensile modulus of from about 400,000 pounds per square inch (psi) to about 2,000,000 psi; a tensile modulus of 900,000 psi is typical; and a preferred tensile modulus of from about 700,000 psi to about 1,200,000 psi. Polydioxanone, polycaprolactone, and polygluconate include tensile modulus of from about 200,000 psi to about 700,000 psi; a tensile modulus of 450,000 psi is typical; and a preferred tensile modulus of from about 350,000 psi to about 550,000 psi.

PLLA filament has a much lower tensile strength and tensile modulus than, for example, Elgiloy® metal alloy wire which may be used to make braided stents. The tensile strength of PLLA is about 22% of the tensile strength of Elgiloy®. The tensile modulus of PLLA is about 3% of the tensile modulus of Elgiloy®. Stent mechanical properties and self-expansion are directly proportional to tensile modu-

lus of the material. As a result, a PLLA filament braided stent made to the same design as the metal stent has low mechanical properties and would not be functional. The invention advantageously provides polymeric braided stents with radial strength similar to metal stents and the required mechanical properties capable of bracing open endoluminal strictures.

A bioabsorbable PLLA braided tubular stent changes size when constrained onto a catheter delivery system and when deployed. A deployed PLLA stent is generally longer in length and smaller in diameter than a PLLA stent prior to loading. For example, PLLA stents that were initially 30 mm long with external diameters of about 10.7 mm had deployed lengths of about 90 mm with diameters of about 6.3 mm.

In comparison, a metal self-expanding stent generally has about the same dimensions before loading and after deployment. For metal stents, if it is known that the patient has a 9 mm diameter vessel, then a 10 mm metal stent (stent is intentionally oversized by about 1 mm) is loaded onto the delivery system for implantation. This rule is not applicable for a polymer stent because more oversizing is necessary.

The present invention provides improved polymeric stents and a method for designing and producing the improved polymeric stents whereby a polymeric stent of a certain size may be produced, loaded on the delivery system, and upon deployment will yield desired implant dimensions and have desired mechanical properties.

The present invention advantageously provides a bioabsorbable PLLA braided stent of a desired implant size, and provides a method to make the stent at a particular diameter (A), anneal the stent at a smaller diameter (B), and deploy the stent from a delivery system of diameter (C) whereby the stent will be "programmed" to self-expand to a desired implant diameter (D). The relationship between the diameters is A>B>D>C.

In sum, the invention relates to a bioabsorbable implantable stent having a tubular, radially compressible and self-expandable braided and annealed structure including a first set of between 5 and 18 filaments, each of which extends in a helix configuration along a center line of the stent and having a first common direction of winding. A second set of filaments of the same number as the first set, each extend in a helix configuration along a center line of the stent and having a second common direction of winding. The second set of filaments cross the first set of filaments at an axially directed angle of between about 120 and about 150 degrees when in a first free radially expanded state after being annealed, but before being loaded on a delivery device so as to form a plurality of interstices between filaments. The term "free state" is used when no externally applied forces are acting on the device, for example, when the device is resting on a table. Each filament includes PLLA, PDLA, PGA, or combinations thereof and have a substantially solid and substantially uniform cross-section, a tensile strength of from about 40 ksi to about 120 ksi, a tensile modulus of from about 400,000 psi to about 2,000,000 psi, and an average diameter of from about 0.15 mm to about 0.6 mm. The first set of filaments and second set of filaments act upon one another to create an outwardly directed radial force sufficient to implant the stent in a body vessel upon deployment from a delivery device. The stent may have a second free radially expanded state after being loaded and then released from a deployment device and the first and second sets of filaments cross at an axially directed angle of between about 80 and about 145 degrees when in the second free radially expanded state. The second sets of filaments may crisscross at an axially directed angle of between about 90 and about 100 degrees when in the second free radially expanded state, and a second free state diameter of from about 3 mm to about 6 mm. The axially directed angle may be between about 110 degrees and about 120 degrees when in the second free radially expanded state. The stent may have an outside diameter when in the second free radially expanded state and the stent exerts an outwardly directed radial force at one half of the outside diameter of from about 40 grams to about 300 grams. The stent may have an implanted state after being loaded, released from a deployment device into a body vessel, and then implanted in the body vessel, with the first and second sets of filaments crossing at an axially directed angle of between about 95 and 105 degrees when the stent is in the implanted state. The stent may be radially constrained to half of its free diameter and the radial force, RF, exerted by the device, in grams, as a function of annealed diameter, D, in mm, is about RF=−15D+491±20. The stent may be annealed at a temperature of from about 60° C. to about 180° C. for a period of time of from about 5 minutes to about 120 minutes. The stent may be annealed at a temperature of from about 130° C. to about 150° C. for a period of time of from about 10 minutes to about 20 minutes. The braid may be annealed to yield a crossing angle of from about 130 degrees to about 150 degrees. The stent may be further disposed in a stent delivery device and the filaments have a crossing angle of from about 30 degrees to about 120 degrees. The stent may be deployed from a delivery system into a body lumen and the filaments have a crossing angle of from about 70 degrees to about 130 degrees. The stent may provide structural integrity to a body lumen for less than about 3 years. The stent may further include polydioxanone, polycaprolactone, polygluconate, polylactic acid-polyethylene oxide copolymers, modified cellulose, collagen, poly(hydroxybutyrate), polyanhydride, polyphosphoester, poly(amino acids) and combinations thereof. The filaments may be mono-filament or multi-filament. The stent may substantially degrade in vivo in from about 1 year to about 2 years. "Substantially degrade" means that the stent has lost at least 50% of its structural strength. It is preferable that the stent lose about 100% of its structural strength. The filaments may include polyglycolide and the stent may substantially degrades in vivo in a time of from about 3 months to about 1 year. The filaments may further include polygluconate, polydioxanone, or combinations thereof and the stent may substantially degrade in vivo in from about 1 week to about 3 months. The stent may have at least one end of diminishing diameter so as to function as a filter. The filaments may be substantially homogeneous in cross section and length. The filaments may have a tensile modulus of from about 400,000 psi to about 1,200,000 psi. The filaments may have a tensile modulus of from about 700,000 psi to about 1,200,000 psi. The stent may include a plurality of the filaments helically wound and interwoven in a braided configuration to form a tube.

The invention also relates to a method of using an implantable endoprosthesis including: providing a tubular, radially compressible, axially flexible, and radially self-expandable braided and annealed structure. The structure including from about 10 to about 36 elongate filaments. The filament comprising PLLA, PDLA, PGA, and combinations thereof. Each filament having a substantially uniform cross-section, a tensile strength of from about 40 ksi to about 120 ksi, and a tensile modulus of from about 400,000 psi to about 2,000,000 psi. The filaments disposed at an angle of from about 130 degrees to about 150 degrees in a free state, each filament having an average diameter of from about 0.15 mm

to about 0.6 mm, and the stent having a radial force at one-half diameter of from about 40 grams to about 300 grams. The annealed structure having a first diameter; disposing the structure into a delivery system at a second diameter smaller than the first diameter, inserting the delivery system and endoprosthesis in a body lumen; deploying the endoprosthesis from the delivery system into the body lumen to a third diameter smaller than the first; and allowing the endoprosthesis to self expand in the body lumen to a fourth diameter greater than the third diameter.

The invention also relates to a method for treating a site within a vessel of a patient, including: providing a biocompatible medical device including a tubular and axially flexible braid-like annealed structure at a first diameter which is radially self-expandable between a compressed state and an expanded state and which includes from about 10 to about 36 elongate filaments. The filaments include PLLA, PDLA, PGA, and combinations thereof. Each filament has a substantially uniform cross-section, a tensile strength of from about 40 ksi to about 120 ksi, and a tensile modulus of from about 400,000 psi to about 2,000,000 psi; Providing a delivery system with the medical device positioned on a portion of the delivery system in the compressed state at a second diameter smaller than the first diameter; Inserting the portion of the delivery system with the medical device into the patient's vessel at a location spaced from the treatment site, and manipulating the delivery system to advance the medical device through the vessel, to the treatment site; Deploying the medical device from the delivery system. The medical device being deployed at a third diameter smaller than the original free diameter and allowing the medical device to self-expand within the vessel; and Removing the delivery system from the patient with the medical device remaining in the expanded state and supporting the vessel.

The invention also relates to a bioabsorbable implantable device made from the process including providing a plurality of elongate filaments including PLLA, PDLA, PGA, and combinations thereof; braiding the filaments on a first mandrel to form a tubular, radially compressible, axially flexible, and radially self-expandable device. The device having a first diameter of from about 2 mm to about 10 mm larger than the final implanted device diameter; and annealing the device on a second mandrel having a second diameter smaller than the first diameter. The second mandrel diameter adapted to be computed from a linear equation relating radial force to annealed stent diameter. The equation being derived from measured radial force and measured annealed stent diameter data from two stent prototypes made on two anneal mandrel diameters and deployed from a device delivery system. Each filament may have a substantially uniform cross-section, a tensile strength of from about 40 ksi to about 120 ksi, and a tensile modulus of from about 400,000 psi to about 2,000,000 psi. Annealing may cause the device to radially shrink.

The invention also relates to a method of manufacturing a stent including: providing from about 10 to about 36 filaments consisting essentially of poly (alpha-hydroxy acid). The filaments have an average diameter from about 0.15 mm to about 0.60 mm; braiding the filaments at a braid angle of from about 120 degrees to about 150 degrees on a braid mandrel of from about 3 mm to about 30 mm diameter; removing the braid from the braid mandrel; disposing the braid on an annealing mandrel having an outer diameter of from about 0.2 mm to about 10 mm smaller than the braid mandrel diameter; annealing the braid at a temperature between about the polymer glass-transition temperature and the melting temperature for a time period between about 5 and about 120 minutes; and allowing the stent to cool.

Bioabsorbable polymer resins are commercially available. Bioabsorbable resins such as PLA, PLLA, PDLA, PGA and other bioabsorbable polymers are commercially available from several sources including PURAC America, Inc. of Lincolnshire, Ill.

Still other objects and advantages of the present invention and methods of construction of the same will become readily apparent to those skilled in the art from the following detailed description, wherein only the preferred embodiments are shown and described, simply by way of illustration of the best mode contemplated of carrying out the invention. As will be realized, the invention is capable of other and different embodiments and methods of construction, and its several details are capable of modification in various obvious respects, all without departing from the invention. Accordingly, the drawing and description are to be regarded as illustrative in nature, and not as restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an isometric view of a stent in accordance with the present invention, illustrating the braided configuration of the filaments;

FIG. **2** is a partial longitudinal cross-sectional view of the stent shown in FIG. **1**;

FIG. **3** is a cross-sectional view of one of the filaments of the stent shown in FIG. **1**;

FIG. **4** is a side view of a delivery device with the stent shown in FIG. **1** loaded thereon;

FIG. **5** is a detailed view of the portion of the delivery device encircled at 5 in FIG. **4**;

FIG. **6** is a detailed view of the portion of the delivery device encircled at 6 in FIG. **4**;

FIGS. **7–10** are partial cross-sectional side views of the distal portion of the delivery device and stent shown in FIG. **4** at various stages during a stent deployment operation in a body vessel;

FIG. **11** is a side view of a pusher-type delivery device;

FIG. **12** is a side view of a second embodiment of a stent in accordance with the present invention;

FIG. **13** is an end view of the stent shown in FIG. **14**;

FIG. **14** is a plot illustrating PLLA stent radial force and deployed diameter vs. annealed stent diameter; and

FIGS. **15–18** are graphs of fatigue test results of PLLA filament batches.

DETAILED DESCRIPTION OF THE INVENTION

A bioabsorbable implantable prosthesis or stent **10** in accordance with the present invention is illustrated generally in FIGS. **1** and **2**. Stent **10** is a tubular device formed from two sets of oppositely-directed, parallel, spaced-apart and helically wound elongated strands or filaments **12**. The sets of filaments **12** are interwoven in an over and under braided configuration intersecting at points such as **14** to form an open mesh or weave construction. As described in greater detail below, at least one and preferably all filaments **12** consists of one or more commercially available grades of polylactide, poly-L-lactide (PLLA), poly-D-lactide (PDLA), polyglycolide (PGA), polydioxanone, polycaprolactone, polygluconate, polylactic acid-polyethylene oxide copolymers, modified cellulose, collagen, poly (hydroxybutyrate), polyanhydride, polyphosphoester, poly (amino acids), poly(alpha-hydroxy acid) or related copoly-

mers materials. Methods for fabricating stents **10** are generally known and disclosed, for example, in the Wallsten U.S. Pat. No. 4,655,771 and the Wallsten et al. U.S. Pat. No. 5,061,275.

Stent **10** is shown in its expanded or relaxed state in FIGS. **1** and 2, i.e., in the configuration it assumes when subject to no external loads or stresses. The filaments **12** are resilient, permitting the radial compression of stent **10** into a reduced-radius, extended-length configuration or state suitable for delivery to the desired placement or treatment site through a body vessel (i.e., transluminally). Stent **10** is also self-expandable from the compressed state, and axially flexible.

Stated another way, stent **10** is a radially and axially flexible tubular body having a predetermined diameter that is variable under axial movement of the ends of the body relative to each other. The stent **10** is composed of a plurality of individually rigid but flexible and elastic thread elements or filaments **12**, each of which extends in a helix configuration along a longitudinal center line of the body as a common axis. The filaments **12** define a radially self-expanding body. The body may be provided by a first number of filaments **12** having a common direction of winding but axially displaced relative to each other, and crossing a second number of filaments **12** also axially displaced relative to each other but having an opposite direction of winding.

The tubular and self-expandable body or structure formed by the interwoven filaments **12** is a primary prosthetically-functional structure of stent **10**, and for this reason the device can be considered to substantially consist of this structure to the exclusion of other structures. However, it is known that other structures and features can be included in stents, and in particular features which enhance or cooperate with the tubular and self-expandable structure or which facilitate the implantation of the structure. One example is the inclusion of radiopaque markers on the structure which are used to visualize the position of the stent through fluoroscopy during implantation. Another example is the inclusion of a covering **15** or additional interwoven filaments, for instance, to reduce the porosity or open spaces in the structure so that the stent can be used to prevent tissue ingrowth or be used as a graft. Other examples include collapsing threads or other structures to facilitate repositioning and removal of the stent. Stents of these types nonetheless still substantially consist of the tubular and self-expandable structure formed by interwoven filaments **12** and shown in FIGS. **1** and **2**. Furthermore, many of the desirable features and properties of stent **10** will be present if some, but not all, of the filaments **12** consist of a bioabsorbable polymeric material.

An implantable bioabsorbable stent **10** may be made by a preferred method of braiding such that 10–36 independent strands of 0.15–0.60 mm diameter bioabsorbable polymeric filament are interwoven into helical shape strands on a round bar mandrel of 3–30 mm diameter such that one-half of the number of helical strands are wound clockwise and one-half are wound counterclockwise and such that each clockwise helical strand is adjacent (interbraided) to a counterclockwise strand, the tubular braid is made with strand braid angles (angle between two filaments in the longitudinal or axial direction) of 120–150 degrees (pitch angles (angle between a filament and transverse axis of the stent) of 15–45 degrees) while on the braid bar mandrel, the braid is slid off of the braid bar and onto a 0.2–10 mm smaller diameter annealing bar or tube mandrel, each end of the braid pulled or compressed to cause axial extension or compression of the braid on the anneal mandrel, or left free, and each end of the braid secured on each end of the anneal mandrel to fix the preset axial position of the braid, or left free, annealing the braid on the anneal mandrel at a temperature between the glass-transition temperature and melting temperature of the polymer for 5–120 minutes in air, vacuum, or inert atmosphere, cooling the annealed braid on the anneal mandrel to about room temperature, sliding the braid off of the anneal mandrel and cutting it to the desired stent length. Another preferred embodiment includes at least one bioabsorbable-radiopaque marker strand.

FIG. **3** is a cross-sectional view of one of the polymeric filaments **12**. As shown, the filaments **12** are substantially homogeneous in cross section.

EXAMPLE 1

Four batches **(53, 54, 55, 56)** of PLLA monofilament **12** were produced by the supplier, Albany International Research Corporation included eight strands collected on separate spools. Four spools were randomly selected from each batch and tested by the supplier. Processing information and supplier test results are set forth below in Table 1.

TABLE 1

Filament Spool No.	Average Diameter, mm	Diameter Standard. Deviation.	Mean Inherent Viscosity Of As Received Filament, Deciliter per gram (dl/g)	Processing History DR = Draw Ratio
53-1	.233	.005	2.89	final DR = 6
53-3	.240	.005	2.98	final DR = 6
53-6	.240	.005	2.86	final DR = 6
53-8	.252	.007	2.78	final DR = 6
54-1	.232	.007	3.23	final DR = 8
54-3	.220	.007	3.31	final DR = 8
54-4	.234	.007	3.22	final DR = 8
54-6	.239	.006	3.14	final DR = 8
55-1	.236	.007	3.29	DR of 8 and mill anneal
55-3	.227	.008	3.32	DR of 8 and mill anneal
55-4	.248	.007	3.28	DR of 8 and mill anneal
55-6	.241	.006	3.20	DR of 8 and mill anneal

TABLE 1-continued

Filament Spool No.	Average Diameter, mm	Diameter Standard. Deviation.	Mean Inherent Viscosity Of As Received Filament, Deciliter per gram (dl/g)	Processing History DR = Draw Ratio
56-1	.237	.016	2.86	final DR of 8 and high extrusion temp.
56-4	.247	.009	2.82	final DR of 8 and high extrusion temp.
56-5	.243	.011	2.83	final DR of 8 and high extrusion temp.
56-6	.246	.009	2.86	final DR of 8 and high extrusion temp.

One spool from each batch was randomly selected for further testing. The PLLA filaments produced in spools **53-8, 54-6, 55-6,** and **56-6** were tested for their mechanical properties in the condition received from the supplier and again tested in an annealed condition. Testing included measurement of the filament diameter, tensile testing, and rotating beam-type fatigue testing. Measurements of mean filament properties in an as-received condition are summarized in Table 2 and measurements of mean filament properties after annealing at 140° C. for 15 minutes are summarized in Table 3.

TABLE 2

Spool #	Diameter, mm	Ultimate Tensile Strength (UTS), MPa	0.2% offset Yield Strength (YS), MPa	% Elongation at break	Modulus, MPa
53-8	.251	384	162	23.5	7102
54-6	.231	628	203	22.6	8826
55-6	.226	676	190	27.6	7447
56-6	.221	659	191	31.7	6550

TABLE 3

Spool #	Diameter, mm	Ultimate Tensile Strength (UTS), MPa	0.2% Offset Yield Strength (YS), MPa	% Elongation at break	Modulus, MPa
53-8	.236	655	141	37.3	3448
54-6	.231	605	181	29.4	6826
55-6	.229	642	181	30.2	6619
56-6	.236	615	172	34.0	5378

Experimentation shows that the diameters of the strands did not change substantially after annealing. The tensile breaking loads were lowest for batch #53 which was drawn at the lowest drawing ratio of 6. The break loads for all four batches ranged from about 4 to 6 lbs. (18 to 28 N) before annealing and the break loads were about the same range after annealing. The mean breaking load was highest for batch #55 which was mill annealed after the final draw ratio of 8. However, after annealing, the difference in mean break loads in the three batches extruded with a draw ratio of 8 was not significant. The mean tensile elongation was highest for batch #56 which was extruded at a higher temperature. The tensile modulus values (Young's modulus) were about one million psi (6895 Mpa) prior to annealing and the tensile modulus values were slightly reduced after annealing, with the exception of batch #53 (DR=6) where the tensile modulus was nearly reduced in half. There were no significant changes in strength or modulus as a result of the annealing at 140° C. for 15 minutes. The annealing was performed to relax and homogenize the material after braiding and to allow the braid to shrink to the desired annealed stent diameter.

Rotating beam bending fatigue testing was performed on annealed specimens from each of the four batches. Testing of the as-extruded filaments was unsuccessful because the filaments did not appear stiff enough to be capable of withstanding torsional loading. However, testing was performed using the Valley Instruments U-bend wire spin fatigue machines. One end of the test specimen was gripped by a chuck, the specimen was formed into an arc, and the free end was inserted into a stationary holder to maintain the arc. The arc dimensions and material modulus were used to calculate the maximum bending stress at the apex of the arc. The specimen was then rotated at 3600 rpm and the surface of the test specimen is cycled between compressive and tensile bending stresses at the apex of the arc. The number of cycles to failure (complete fracture, kinking, or longitu-

dinal splitting) was recorded for each test, and the results are plotted in a stress vs. cycles to failure plot (SIN fatigue plots in FIGS. **15–18**).

Batch #53, with the lowest draw ratio of 6, had lower fatigue results or failures at lower stresses than the batches extruded at the higher draw ratio of 8. Batches #54 and #55 had similar fatigue results, and batch #56 had lower results than #54 and #55, but had higher results than 53. The results indicate that the higher draw ratio and lower extrusion temperatures are preferred if fatigue strength is to be maximized.

EXAMPLES 2–10

A stent **10** was fabricated from about 0.24 mm diameter PLLA monofilament **12** from spool **55-6**. This spool was selected because it had high UTS and modulus which are desirable mechanical properties for obtaining high stent radial strength. The stent **10** was braided onto a 10 mm diameter steel bar mandrel. The braid was constructed of 24 strands and the braid angle was 130 degrees (pitch angle of 25 degrees). The included angle between interbraided filaments in the axial orientation is termed "braid angle" prior to annealing and is termed "filament crossing angle" after annealing. A braid becomes a stent after annealing.

Braid annealing was performed to relax the stresses in the filaments resulting from braiding and to set the stent shape. Three anneal trials were performed. In the first trial, the braid was slid onto a 10 mm diameter tubular mandrel. In this trial, the braid was difficult to put on the mandrel because the braid inside diameter was very close to the mandrel diameter. In the second trial, the braid was easily put onto a 9 mm diameter mandrel. The braid was compressed axially and held in this state with plastic tie-wraps. The third trial was performed in the same manner as the second trial.

After annealing, the braid had shrunk down onto the anneal mandrel and the annealed filament crossing angle was higher than the original braid angle. The annealed uncut stents were measured with a laser micrometer for external diameter. A scale was used to measure pitch length. The results are presented in the following Table 4.

TABLE 4

Dimension	Trial #1	Trial #2	Trial #3
Average External Diameter, mm	10.65	9.83	9.87
Pitch Length, mm	10.34	10.34	10.08
Calculated Filament Crossing Angle, °	145	143	144

The average external diameter is the average value of the external stent diameters measured. The pitch length is the length of one complete filament helix. The filament crossing angle was calculated from the average external diameter and the pitch length using the equation, angle=$180° - 2\mathrm{Tan}^{-1}(P/\pi D)$, where p is the pitch length and D is the average external stent diameter minus twice the filament diameter.

The uncut stents **10** were then cut to 30 mm lengths at the free diameter and were loaded onto 10 French catheter delivery systems. The delivery system is constructed of an inner tube which slides over the guidewire in an angioplasty procedure and an outer tube. The stent is axially extended and radially contracted onto the outer surface of the inner tube and the outer tube is slid coaxially over the constrained stent to hold it in the constrained condition. When the delivery system is positioned in the stricture to be treated, the outer tube is pulled back allowing the stent to spring off of the inner tube and self-expand to brace open the stricture. The nominal outer tube inner diameter was 2.8448 mm and the inner tube outer diameter was 1.3208 mm. The calculated gap between the inner and outer tube was 0.7642 mm. The stents **10** were left on the delivery systems for 30 minutes and were then were deployed onto the benchtop.

Dimensions of the nine 10 mm PLLA stents **10** before loading and after deployment are listed in Table 5.

TABLE 5

Trial #	Initial Length, mm	Deployed Length, mm	Initial Diameter, mm	Deployed Diameter, mm	Self-expansion (deployed/initial Ø)
1a	32	90	10.69	6.2	0.58
1b	30	88	10.73	6.6	0.62
1c	30	90	10.63	6.2	0.58
2a	30	80	9.94	5.2	0.52
2b	30	68	9.83	6.2	0.63
2c	30	80	9.88	6.4	0.65
3a	30	80	9.96	5.0	0.50
3b	30	80	9.76	5.7	0.58
3c	30	80	9.80	5.6	0.57

Initial length and diameter were measured on the cut stent in its free state on the table after annealing but before being loaded for deployment. Deployed length and diameter were measured after the annealed stent was loaded on the 10 French delivery system and deployed on the table and allowed to reach its free state. The lengths of stents upon implantation will be longer upon implantation because the stent will only reach about 80% of the deployed diameter when implanted.

The stent dimensional changes resulting from loading appeared consistent from test specimen to test specimen. The stents **10** were deformed by the constraint on the delivery system. This consistency allows the dimensional changes to be anticipated and accounted for during design. The dimensions of deployed stents **10** were considerably changed relative to the dimensions of the same stents **10** prior to loading. The deformation was not permanent and the stents **10** reverted toward the original dimensions over a period of days after deployment. For instance, the stents **10** from trial #1 opened up to almost 90% of their original pre-loaded diameter after about 3 days from the deployment time.

Residual stresses appear to remain in the material from delivery system constraint and are relieved at room temperature over a period of time which allows stent **10** to return toward its original undeformed condition. If the residual stresses can be minimized, or if the magnitude of the residual stresses relative to the yield strength can be minimized, or if stress relief can be accelerated to seconds instead of days, it may be possible to increase the amount of self-expansion immediately upon deployment. In order to avoid imparting significant residual stresses, loading is preferably performed with less stressing of the stent **10**, i.e., use of a larger profile delivery system, use of a larger gap between inner and outer tubes, a gentle loading technique, or use of an alternate delivery system design.

The use of a pusher-type delivery system results in greater self-expansion of the stent than a coaxial inner-outer tube-type delivery system as shown in FIG. **11**. Reference is made to U.S. Pat. No. 4,954,126. For example, pushing the proximal end of the stent out the distal end of the delivery system results in more self expansion than when the stent is released by sliding back the outer tube of the catheter delivery system because the stent **10** is under axial compression during deployment.

EXAMPLE 11–15

Experiments were performed using various PLLA monofilament braided stents **10**. The stents **10** were annealed on various sized tubular anneal mandrels and then loaded and deployed from delivery systems. The 36 French delivery systems pushed the stent **10** out of a stainless steel outer tube. The 10 and 18 French delivery systems were inner and outer tube catheter type systems where the outer tube is pulled back to allow the stent to spring open. The external diameter of the stents **10** were measured after annealing and after deployment from the delivery system. Radial force testing was performed on deployed stents **10** by wrapping a metal wire around the stent circumference at the center of the stent length and pulling on each end of the wire to cause radial contraction of the stent diameter to one-half of its original (free) value. The ends of the wire were attached to a load cell to measure the force necessary to cause radial contraction.

The braid mandrel diameter is the external diameter of the braid bar. The delivery system size is the external diameter in French size (or about three times the diameter in mm). Deployed stent external diameter and radial force were measured on stents released from the delivery system onto the table. Percent self-expansion is (deployed diameter/annealed diameter)×100.

The experimental results for PLLA braided stent load and deployment trials and radial force testing are shown in Table 6 below. The inner/outer tube catheter type of delivery system yielded lower percent self-expansion than the pusher type of delivery system (58–76% vs. 85–93%, respectively).

TABLE 6

# Of Filaments In Braid	Filament Diameter, Mm	Braid Mandrel Dia., Mm	Anneal Mandrel Dia., Mm	Annealed Stent External Dia., Mm	Delivery System Size, French	Deployed Stent External Dia., Mm	Percent Self-Expansion	Radial Force At Half-Stent Dia., Grams
24	.25	10.0	9.0	9.9	10	5.7	58	64
30	.35	18.5	18.0	19.1	18	14.5	76	90
36	.36	25.8	18.0	19.4	36	16.4	85	200
36	.36	25.8	22.0	23.3	36	19.7	85	132
36	.36	25.8	24.0	25.2	36	23.4	93	113

Experimentation has shown that there is a nearly linear relationship between stent radial force and annealed stent diameter for a given braid design and delivery system design. The present invention provides a method to determine the preferred anneal mandrel size for a particular polymeric stent **10** design. For example, if a PLLA braided filament stent **10** is desired to have a radial force equal to a particular metal stent or polymer stent, the radial force of the benchmark stent can be measured and used as the target value. Further, a stent **10** of a size at or about the desired implant size from Table 7 above would then be annealed on two different sizes of anneal mandrels and the radial force of the deployed annealed stents would be measured. The slope and intercept values would be calculated from the test results. The linear equation can then be used to solve for the annealed stent diameter which will yield the target radial force value. Example 16 below illustrates the methodology.

EXAMPLE 16

The radial force data in Table 6 for the 36-filament stents was plotted against the values for annealed stent diameter and is illustrated in FIG. **13** for stents **10** with 36 strands of 0.36 mm diameter PLLA filament annealed at 140° C. for 15 minutes and deployed from a 36 French pusher-type delivery system.

The graph is nearly linear. The slope and intercept were calculated using two sets of coordinates from the line (200 g, 19.4 mm and 113 g, 25.2 mm).

RF (g)=m (ann Ø)+b where m is the slope and b is the intercept.

m=200−113/19.4−25.2=−15

200=(−15)(19.4)+=491

RF (*g*)=(−15)(annØ)+491 Equation 1 (36-filament PLLA stent)

For example, if the target value for radial force is 150 g:

150=(−15)(ann Ø)+491

annealed stent diameter=22.73 mm

anneal mandrel diameter=stent diameter−4*d* where *d* is the filament diameter

anneal mandrel diameter=21.29 mm

Accordingly, it is possible to manufacture a bioabsorbable stent which is predicted to yield a desired radial force after deployment from the delivery system. For example, from Table 6 or 7, a stent **10** design of 36 strands has a 0.36 mm diameter PLLA filament. The stent **10** can be then annealed on a 21.29 mm diameter tubular mandrel. The annealed stent **10** can be loaded onto a 36 French pusher delivery system for implantation.

Similar experimentation was used to predict the deployed stent diameter (implant size) from the annealed stent diam-

eter for a given braid design and delivery system size. A graph of the deployed stent diameter vs. annealed stent diameter is nearly linear, so a linear equation is used to predict the deployed stent diameter. Two stents **10** were made from two different anneal mandrel sizes and then loaded and deployed from the delivery system. The linear equation can be determined from the experimental results. Subsequently, the linear equation is used to predict the anneal mandrel size necessary to yield a target implant size.

EXAMPLE 17

The deployed stent diameter data in Table 6 for the 36 filament stents was plotted against the values for annealed stent diameter (FIG. **13**). The graph is nearly linear. The slope and intercept were calculated using two sets of coordinates from the line (16.4 mm, 19.4 mm and 23.4 mm, 25.2 mm).

deployed Ø=*m* (ann Ø)+*b* where *m* is the slope and *b* is the intercept.

m=16.4−23.4/19.4−25.2=1.21

16.4=(1.21)(19.4)+*b* *b*=7.07

deployed Ø=(1.21)(ann Ø)−7.07 Equation 2 (36-filament PLLA stent)

For example, if the target value for deployed diameter is 20 mm:

20=(1.21)(ann Ø)−7.07

annealed stent diameter=22.37 mm

anneal mandrel diameter=stent diameter−4*d* where *d* is the filament diameter

anneal mandrel diameter=20.93 mm

Accordingly, the present invention provides a bioabsorbable stent which provides a desired radial force and diameter after deployment from the delivery system. For example, from Table 6 or 7, a stent **10** design of 36 strands has a 0.36 mm diameter PLLA filament. The stent **10** can be annealed on a 20.93 mm diameter tubular mandrel and loaded onto a 36 French pusher delivery system for implantation. Furthermore, the stent **10** would yields a radial force of about 155 grams as previously shown.

Using linear equations to predict the annealed stent diameter and radial force minimizes the total number of design iterations for manufacturing and testing. Only two designs must be made to allow the predictive equations to be developed.

The PLLA filament stent **10** from Table 7 may be used with the required delivery system. The linear equations can be derived using the two test series, and thereafter the stent design may be optimized with regard to radial force and implant size by predicting the necessary anneal mandrel size.

TABLE 7

# of filament strands in stent	braid mandrel diameter, mm	braid angle, degrees	PLLA diameter, mm	PDLA diameter, mm	PLLA/PDLA diameter, mm	PGA diameter, mm
10	3–6	120–150	.15–.25	.15–.25	.15–.25	.20–.30
10	3–6	120–150	.20–.30	.20–.30	.20–.30	.25–.35
12	3–8	120–150	.20–.30	.20–.30	.20–.30	.25–.35
12	3–8	120–150	.35–.45	.35–.45	.35–.45	.40–.50
15	6–10	120–150	.30–.40	.30–.40	.30–.40	.35–.45
15	6–10	120–150	.35–.45	.35–.45	.35–.45	.40–.50
18	7–12	120–150	.35–.45	.35–.45	.35–.45	.40–.50
18	7–12	120–150	.40–.50	.40–.50	.40–.50	.45–.55
20	3–9	120–150	.20–.30	.20–.30	.20–.30	.25–.35
24	8–12	120–150	.20–.30	.20–.30	.20–.30	.25–.35
24	9–14	120–150	.25–.35	.25–.35	.25–.35	.30–.40
24	12–18	120–150	.30–.40	.30–.40	.30–.40	.35–.45
30	16–26	120–150	.30–.40	.30–.40	.30–.40	.35–.45
36	20–30	120–150	.35–.45	.35–.45	.35–.45	.40–.50
24	14–20	120–150	.35–.45	.35–.45	.35–.45	.40–.50

# of filament strands in braid	braid mandrel diameter, mm	braid angle, degrees	PGA/PLLA diameter, mm	PGA/ polycaprolactone diameter, mm	Polydioxanone diameter, mm	PGA/trimethylene carbonate diameter, mm
10	3–6	120–150	.20–.30	.22–.32	.25–.35	.22–.32
10	3–6	120–150	.25–.35	.27–.37	.30–.40	.27–.37
12	3–8	120–150	.25–.35	.27–.37	.30–.40	.27–.37
12	3–8	120–150	.40–.50	.42–.52	.45–.55	.42–.52
15	6–10	120–150	.35–.45	.37–.47	.40–.50	.37–.47
15	6–10	120–150	.40–.50	.42–.52	.45–.55	.42–.52
18	7–12	120–150	.40–.50	.42–.52	.45–.55	.42–.52
18	7–12	120–150	.45–.55	.47–.57	.50–.60	.47–.57
20	3–9	120–150	.25–.35	.27–.37	.30–.40	.27–.37
24	8–12	120–150	.25–.35	.27–.37	.30–.40	.27–.37
24	9–14	120–150	.30–.40	.32–.42	.35–.45	.32–.42
24	12–18	120–150	.35–.45	.37–.47	.40–.50	.37–.47
30	16–26	120–150	.35–.45	.37–.47	.40–.50	.37–.47
36	20–30	120–150	.40–.50	.42–.52	.45–.55	.42–.52
24	14–20	120–150	.40–.50	.42–.52	.45–.55	.42–.52

The experiments indicate that stents **10** fabricated from the PLLA filament have desirable characteristics for certain applications. The stents **10** have measurable resistance to compression and exert a more gentle force (less radial force) than the Elgiloy® stent on the lumen wall. Stents **10** are therefore durable and flexible, and capable of being moved

through curved vessels or lumens during delivery. The PLLA material is highly biocompatible.

Although PLLA is the most preferred absorbable polymer, other polymers can also be used. In particular, poly-D-lactide (PDLA), polyglycolide (PGA), polydioxanone, polycaprolactone, polygluconate, polylactic acid-polyethylene oxide copolymers, modified cellulose, collagen, poly(hydroxybutyrate), polyanhydride, polyphosphoester, poly(amino acids), or related copolymers materials will offer advantages similar to the most preferred polymer.

EXAMPLE 18

Stents **10** can be fabricated from 10 filament strands of 0.15–0.25 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.20–0.30 mm diameter PGA, PGA-PLLA copolymer, 0.22–0.32 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.25–0.35 mm diameter polydioxanone on a 3–6 mm diameter braid mandrel with a filament braid angle of 120–150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2–10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5–120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel, cut to the desired stent length, and loaded onto a delivery system at least 5 French in size.

EXAMPLE 19

Stents **10** can be fabricated from 10 filament strands of 0.20–0.30 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.25–0.35 mm diameter PGA, PGA-PLLA copolymer, 0.27–0.37 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.30–0.40 mm diameter polydioxanone on a 3–6 mm diameter braid mandrel with a filament braid angle of 120–150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2–10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5–120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel, cut to the desired stent length, and loaded onto a delivery system at least 7 French in size.

EXAMPLE 20

Stents **10** can be fabricated from 12 filament strands of 0.20–0.30 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.25–0.35 mm diameter PGA, PGA-PLLA copolymer, 0.27–0.37 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.30–0.40 mm diameter polydioxanone on a 3–8 mm diameter braid mandrel with a filament braid angle of 120–150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2–10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5–120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel, cut to the desired stent length, and loaded onto a delivery system at least 7 French in size.

EXAMPLE 21

Stents **10** can be fabricated from 12 filament strands of 0.35–0.45 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.40–0.50 mm diameter PGA, PGA-PLLA copolymer, 0.42–0.52 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.45–0.55 mm diameter polydioxanone on a 3–8 mm diameter braid mandrel with a filament braid angle of 120–150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2–10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5–120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel, cut to the desired stent length, and loaded onto a delivery system at least 10 French in size.

EXAMPLE 22

Stents **10** can be fabricated from 15 filament strands of 0.30–0.40 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.35–0.45 mm diameter PGA, PGA-PLLA copolymer, 0.37–0.47 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.40–0.50 mm diameter polydioxanone on a 6–10 mm diameter braid mandrel with a filament braid angle of 120–150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2–10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5–120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel, cut to the desired stent length, and loaded onto a delivery system at least 8 French in size.

EXAMPLE 23

Stents **10** can be fabricated from 15 filament strands of 0.35–0.45 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.40–0.50 mm diameter PGA, PGA-PLLA copolymer, 0.42–0.52 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.45–0.55 mm diameter polydioxanone on a 6–10 mm diameter braid mandrel with a filament braid angle of 120–150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2–10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5–120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel, cut to the desired stent length, and loaded onto a delivery system at least 10 French in size.

EXAMPLE 24

Stents **10** can be fabricated from 18 filament strands of 0.35–0.45 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.40–0.50 mm diameter PGA, PGA-PLLA copolymer, 0.42–0.52 mm diameter PGA-polycaprolactone

copolymer, PGA-trimethylcarbonate copolymer, or 0.45–0.55 mm diameter polydioxanone on a 7–12 mm diameter braid mandrel with a filament braid angle of 120–150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2–10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5–120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel, cut to the desired stent length, and loaded onto a delivery system at least 10 French in size.

EXAMPLE 25

Stents **10** can be fabricated from 18 filament strands of 0.40–0.50 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.45–0.55 mm diameter PGA, PGA-PLLA copolymer, 0.47–0.57 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.50–0.60 mm diameter polydioxanone on a 7–12 mm diameter braid mandrel with a filament braid angle of 120–150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2–10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5–120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel, cut to the desired stent length, and loaded onto a delivery system at least 12 French in size.

EXAMPLE 26

Stents **10** can be fabricated from 20 filament strands of 0.20–0.30 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.25–0.35 mm diameter PGA, PGA-PLLA copolymer, 0.27–0.37 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.30–0.40 mm diameter polydioxanone on a 3–9 mm diameter braid mandrel with a filament braid angle of 120–150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2–10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5–120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel, cut to the desired stent length, and loaded onto a delivery system at least 9 French in size.

EXAMPLE 27

Stents **10** can be fabricated from 24 filament strands of 0.20–0.30 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.25–0.35 mm diameter PGA, PGA-PLLA copolymer, 0.27–0.37 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.30–0.40 mm diameter polydioxanone on a 8–12 mm diameter braid mandrel with a filament braid angle of 120–150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2–10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5–120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel, cut to the desired stent length, and loaded onto a delivery system at least 10 French in size.

EXAMPLE 28

Stents **10** can be fabricated from 24 filament strands of 0.25–0.35 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.30–0.40 mm diameter PGA, PGA-PLLA copolymer, 0.32–0.42 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.35–0.45 mm diameter polydioxanone on a 9–14 mm diameter braid mandrel with a filament braid angle of 120–150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2–10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5–120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel, cut to the desired stent length, and loaded onto a delivery system at least 12 French in size.

EXAMPLE 29

Stents **10** can be fabricated from 24 filament strands of 0.30–0.40 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.35–0.45 mm diameter PGA, PGA-PLLA copolymer, 0.37–0.47 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.40–0.50 mm diameter polydioxanone on a 12–18 mm diameter braid mandrel with a filament braid angle of 120–150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2–10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5–120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel, cut to the desired stent length, and loaded onto a delivery system at least 13 French in size.

EXAMPLE 30

Stents **10** can be fabricated from 30 filament strands of 0.30–0.40 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.35–0.45 mm diameter PGA, PGA-PLLA copolymer, 0.37–0.47 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.40–0.50 mm diameter polydioxanone on a 16–26 mm diameter braid mandrel with a filament braid angle of 120–150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2–10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5–120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel, cut to the desired stent length, and loaded onto a delivery system at least 14 French in size.

EXAMPLE 31

Stents **10** can be fabricated from 36 filament strands of 0.35–0.45 mm diameter PLLA, PDLA, PLLA-PDLA

copolymer, 0.40–0.50 mm diameter PGA, PGA-PLLA copolymer, 0.42–0.52 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.45–0.55 mm diameter polydioxanone on a 20–30 mm diameter braid mandrel with a filament braid angle of 120–150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2–10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5–120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel, cut to the desired stent length, and loaded onto a delivery system at least 18 French in size.

EXAMPLE 32

Stents **10** can be fabricated from 24 filament strands of 0.35–0.45 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.40–0.50 mm diameter PGA, PGA-PLLA copolymer, 0.42–0.52 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.45–0.55 mm diameter polydioxanone on a 14–20 mm diameter braid mandrel with a filament braid angle of 120–150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2–10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5–120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel, cut to the desired stent length, and loaded onto a delivery system at least 14 French in size.

FIGS. **4–6** are illustrations of a coaxial inner/outer tube catheter delivery device **20** for delivering stent **10** to a treatment site in a body vessel. An extension tube **45** extends from side port **41** to an opening **42**.

As shown, stent **10** may be carried by the distal portion of delivery device **20**, and is placed on the delivery device in a radially contracted or compressed state. The proximal portion of delivery device **20** generally remains outside of the body for manipulation by the operator.

The manner by which delivery device **20** is operated to deliver stent **10** to a treatment site in a body vessel or lumen including curved sections is illustrated in FIGS. **7–10**.As shown, stent **10** is placed in a radially compressed state in a surrounding relationship to the outer distal end of inner tube **30**. A tip **31** is disposed at the distal end of tube **30**. Stent **10** is constrained on inner tube **30** by the double-walled section of hose **55**. It is important that stent **10** not be confined too tightly on inner tube **30**. Hose **55** should apply just enough force to stent **10** to hold stent **10** in place. The double-walled section of hose **55** can be removed from around stent **10** by pulling valve body **40** and proximal tube **50** in a proximal direction. The double-walled section "rolls" off stent **10**. No sliding movements take place between stent **10** and inner wall **56** which contacts stent **10**. Holes **59** are located in the double wall section of the hose **55**. Along with the movement of the double-walled section in a proximal direction, the distal end of stent **10** will be exposed in a radial direction to engagement against the wall of the body vessel. As the double-walled section of hose **55** continues moving proximally, more of stent **10** expands in a radial direction until the entire length of stent **10** is exposed and engages the wall of a body vessel.

Lumen **35** is used to enable delivery device **20** to follow a guide wire (not shown) previously inserted percutaneously into the body vessel. The lumen of inner tube **30** can also be used to introduce a contrast fluid to the area around the distal end of delivery device **20** so the position of delivery device **20** can be detected (e.g., through the use of fluoroscopy or X-ray techniques).

FIG. **11** illustrates a delivery device with an outer tube **61** including member **63** and an inner tube **62** including members **64, 65**. Stent **10** may be disposed in region **66** and one position of member **65** is shown at about region **67**. Member **64** may move in the direction of arrow **68** to push the stent out through end **70** into contact with the interior of wall **72**. The stent **10** is shown as lines **69, 71**. The end **70** may be moved by moving member **63** in the direction of arrow **73**.

The stents of the present invention may be delivered by alternative methods or using alternative devices. For instance, the device described in Heyn et al. U.S. Pat. No. 5,201,757 may be utilized.

Another embodiment of the present invention, stent **110**, is illustrated in FIGS. **12** and **13**. Stent **110** is similar to stent **10** described above in that it is a tubular device formed from two sets of oppositely-directed, parallel, spaced-apart and helically wound elongated strands or filaments **112**. The sets of filaments **112** are interwoven in an over and under braided configuration intersecting at points such as **114** to form an open mesh or weave construction. One end **116** of stent **110** is tapered and has a diameter which decreases from the diameter of the other portions of the stent to a reduced diameter. Stent **110** can be otherwise identical in structure and fabricated from the same PLLA or absorbable polymer materials as stent **10** described above. Stent **110** can be applied (in the manner of stent **10** described above) to a desired location within a vessel, for example, Vena Cava Inferior, for the purpose of preventing lung emboly. When used in this application, stent **110** can be inserted into Vena Cava with a high degree of precision and functions as a filter.

Stents **10** and **110** offer considerable advantages. In particular, the polymers from which they are formed are highly biocompatible and exhibit good resistance to thrombosis and bacteria adhesion. The stents **10** and **110** have a relatively low elastic modulus, moderately low strength, and high ductility. They are therefore durable yet sufficiently flexible that they can be delivered to treatment sites through curved body vessels. The PLLA stents **10** and **110** may exert a gentler radial force against the lumen wall than would the current Elgiloy® stent. The radial force could be made to be higher or lower by utilizing larger or smaller diameter filament in the stent construction.

Although the present invention has been described with reference to preferred embodiments, those skilled in the art will recognize that changes can be made in form and detail without departing from the spirit and scope of the invention.

It will be evident from considerations of the foregoing that the bioabsorbable self-expanding stent **10** may be constructed using a number of methods and materials, in a wide variety of sizes and styles for the greater efficiency and convenience of a user.

Another bioabsorbable stent that may advantageously be used in conjunction with the present invention is disclosed in J. Stinson's United States Patent Application entitled "Bioabsorbable Implantable Endoprosthesis With Reservoir And Method Of Using Same", Ser. No. 08/905,806 filed concurrently herewith, and commonly assigned to the assignee of this application.

A bioabsorbable marker that may advantageously be used in conjunction with the present invention is disclosed in J.

Stinson's and Claude Clerc's United States Patent Application entitled "Radiopaque Markers And Methods Of Using Same", Ser. No. 08/905,821, filed concurrently herewith, and commonly assigned to the assignee of this application.

Another bioabsorbable marker that may advantageously be used in conjunction with the present invention is disclosed in J. Stinson's United States Patent Application entitled "Bioabsorbable Marker Having Radiopaque Constituents And Method Of Using Same", Ser. No. 08/904,951, filed concurrently herewith, and commonly assigned to the assignee of this application.

The above described embodiments of the invention are merely descriptive of its principles and are not to be considered limiting. Further modifications of the invention herein disclosed will occur to those skilled in the respective arts and all such modifications are deemed to be within the scope of the invention as defined by the following claims.

What is claimed is:

1. A bioabsorbable implantable stent having a tubular, radially compressible and self-expandable braided and annealed structure comprising:

a first set of between 5 and 18 filaments each of which extends in a helix configuration along a center line and having a first common direction of winding;

a second set of filaments of the same number as the first set, each of which extends in a helix configuration along the center line and having a second common direction of winding;

the second set of filaments crossing the first set of filaments at an axially directed angle of between about 120 and about 150 degrees when in a first free radially expanded state after being annealed but before being loaded on a delivery device so as to form a plurality of interstices between filaments, and further to determine an annealed diameter, D, of the stent in said first free radially expanded state;

each filament comprising at least one of poly-L-lactide, poly-D-lactide, polyglycolide and combinations thereof, and having a substantially solid and substantially uniform cross-section, a tensile strength of from about 40 ksi to about 120 ksi, a tensile modulus of from about 400,000 psi to about 2,000,000 psi, and an average diameter of from about 0.15 mm to about 0.6 mm;

wherein the first set of filaments and second set of filaments act upon one another to create an outwardly directed radial force sufficient to implant the stent in a body vessel upon deployment from the delivery device; and

wherein said radial force, when the stent is radially constrained to a predetermined fraction of the annealed diameter, varies substantially linearly as a function of the annealed diameter, whereby said annealed diameter, D, is selected to provide a desired radial force when the stent is so radially constrained.

2. The stent of claim **1** wherein the stent has a second free radially expanded state after being loaded and then released from a deployment device, the first and second sets of filaments crossing at an axially directed angle of between about 80 and about 145 degrees when in the second free radially expanded state.

3. The stent of claim **1** wherein the stent has a second free radially expanded state after being loaded and then released from a deployment device, the first and second sets of filaments crossing at an axially directed angle of between about 90 and about 100 degrees when in the second free radially expanded state, and a second free state diameter of from about 3 mm to about 6 mm.

4. The stent of claim **2** wherein the axially directed angle is between about 110 degrees and about 120 when in the second free radially expanded state.

5. The stent of claim **2** wherein the stent has an outside diameter when in the second free radially expanded state and the stent exerts an outwardly directed radial force at one half of the outside diameter of from about 40 grams to about 300 grams.

6. The stent of claim **2** wherein the stent has an implanted state after being loaded, released from a deployment device into a body vessel, and then implanted in the body vessel, with the first and second sets of filaments crossing at an axially directed angle of between about 95 and about 105 degrees when the stent is in the implanted state.

7. The bioabsorbable implantable stent of claim **1** wherein the stent is radially constrained to half of its free diameter whereby said predetermined fraction is one-half, and the radial force, RF, exerted by the stent, in grams, as a function of the annealed diameter, D, in mm, is about RF=−15D+491 ±20.

8. The bioabsorbable implantable stent of claim **1** wherein the stent is annealed at a temperature of from about 60° C. to about 180° C. for a period of time of from about 5 minutes to about 120 minutes.

9. The bioabsorbable implantable stent of claim **1** wherein the stent is annealed at a temperature of from about 1 30° C. to about 150° C. for a period of time of from about 10 minutes to about 20 minutes.

10. The bioabsorbable implantable device of claim **1** wherein the stent is annealed to yield a crossing angle of from about 130 degrees to about 150 degrees.

11. The bioabsorbable implantable stent of claim **1** wherein the stent is further disposed in a stent delivery device and the filaments have a crossing angle of from about 30 degrees to about 120 degrees.

12. The bioabsorbable implantable stent of claim **1** wherein the stent is deployed from a delivery system into a body lumen and the filaments have a crossing angle of from about 70 degrees to about 130 degrees.

13. The bioabsorbable implantable stent of claim **1** wherein the stent provides structural integrity to a body lumen for less than about 3 years.

14. The bioabsorbable implantable stent device of claim **1** wherein the stent further comprises polydioxanone, polycaprolactone, polygluconate, polylactic acid-polyethylene oxide copolymers, modified cellulose, collagen, poly(hydroxybutyrate), polyanhydride, polyphosphoester, poly(amino acids) and combinations thereof.

15. The bioabsorbable implantable stent of claim **1** wherein the filaments are mono-filament or multi-filament.

16. The bioabsorbable implantable stent of claim **1** wherein the stent substantially degrades in vivo in from about 1 year to about 2 years.

17. The bioabsorbable implantable stent of claim **1** wherein the filaments comprise polyglycolide and whereby the stent substantially degrades in vivo in a time of from about 3 months to about 1 year.

18. The bioabsorbable implantable stent of claim **1** wherein the filaments further comprise polygluconate, polydioxanone, or combinations thereof and whereby the stent substantially degrade in vivo in from about 1 week to about 3 months.

19. The bioabsorbable implantable stent of claim **1** wherein the stent has at least one end of diminishing diameter so as to function as a filter.

20. The bioabsorbable implantable stent device of claim 1 wherein the filaments are substantially homogeneous in cross section and length.

21. The bioabsorbable implantable stent of claim 1 wherein the filaments have a tensile modulus of from about 400,000 psi to about 1,200,000 psi.

22. The bioabsorbable implantable stent of claim 1 wherein the filaments have a tensile modulus of from about 700,000 psi to about 1,200,000 psi.

23. The bioabsorbable implantable stent of claim 1 wherein the stent includes a plurality of the filaments helically wound and interwoven in a braided configuration to form a tube.

24. A bioabsorbable implantable endoprosthesis comprising:

a first set of filaments each of which extends in a configuration about a center line and having a first common direction of winding;

a second set of filaments each of which extends in a configuration about the center line and having a second common direction of winding;

the second set of filaments crossing the first set of filaments at an axially directed angle of between about 120 and about 150 degrees when in a free radially expanded state after being annealed, to determine an annealed diameter, D, of the endoprosthesis in said free radially expanded state;

each filament comprising a bioabsorbable material having a tensile strength of from about 15 ksi to about 120 ksi, a tensile modulus of from about 200,000 psi to about 2,000,000 psi, and an average thickness of from about 0.15 mm to about 0.6 mm;

wherein the first set of filaments and second set of filaments act upon one another to create an outwardly directed radial force and the bioabsorbable implantable endoprosthesis is adapted to substantially degrade in less than about 3 years; and

wherein said radial force, when the endoprosthesis is radially constrained to a predetermined fraction of the annealed diameter, varies substantially linearly as a function of the annealed diameter, whereby the annealed diameter, D, is selected to provide a desired force when the endoprosthesis is so radially constrained.

25. The bioabsorbable implantable endoprosthesis of claim 24 wherein after the bioabsorbable implantable endoprosthesis is radially constrained to about half of its free radially expanded diameter, whereby said predetermined fraction is one-half, the radial force RF exerted in grams, as a function of the annealed diameter, D in mm, is defined by about RF=−15D+491±20.

26. The bioabsorbable implantable endoprosthesis of claim 24 wherein the bioabsorbable implantable endoprosthesis is adapted to provide structural integrity to a body lumen for less than about 3 years.

27. The bioabsorbable implantable endoprosthesis of claim 24 wherein the bioabsorbable implantable endoprosthesis include poly(alpha-hydroxy) acid.

28. The bioabsorbable implantable endoprosthesis of claim 24 wherein the filaments include at least one of polydioxanone, polycaprolactone, polygluconate, polylactic acid-polyethylene oxide copolymers, modified cellulose, collagen, poly(hydroxybutyrate), polyanhydride, polyphosphoester, poly(amino acids) and combinations thereof.

29. The bioabsorbable implantable endoprosthesis of claim 24 wherein the bioabsorbable implantable endoprosthesis substantially degrades in vivo in from about 1 year to about 2 years.

30. The bioabsorbable implantable endoprosthesis of claim 28 wherein the filaments consist of polyglycolide and the bioabsorbable implantable endoprosthesis substantially degrades in vivo in from about 3 months to about 1 year.

31. The bioabsorbable implantable endoprosthesis of claim 28 wherein the filaments include at least one of polygluconate and polydioxanone and the bioabsorbable implantable endoprosthesis substantially degrades in vivo in from about 1 week to about 3 months.

32. The bioabsorbable implantable endoprosthesis of claim 24 wherein the filaments are substantially homogeneous in cross section and length.

33. The bioabsorbable implantable endoprosthesis of claim 24 wherein the filaments form a tube.

34. A bioabsorbable implantable endoprosthesis, including:

a first set of bioabsorbable filaments wound helically in a first common direction;

a second set of bioabsorbable filaments wound in a second common direction different than the first common direction, and cooperating with the first set of filaments to form a prosthesis structure in which the filaments of the first and second sets cross one another at an axially directed angle when in a free radially expanded state after being annealed, to determine an annealed diameter D of the prosthesis structure in the free radially expanded state; and

wherein the first set of filaments and the second set of filaments cooperate to provide an outwardly directed radial force when the prosthesis structure is radially constrained to a diameter less than the annealed diameter D, and wherein said radial force, when the prosthesis structure is radially constrained to a predetermined fraction of the annealed diameter, varies substantially linearly as a function of the annealed diameter, whereby the annealed diameter D is selectable to provide a desired radial force when the prosthesis structure is radially constrained to said predetermined fraction of the annealed diameter.

35. The endoprosthesis of claim 34 wherein:

said axially directed angle is between about 120 degrees and about 150 degrees.

36. The endoprosthesis of claim 34 wherein:

each of the filaments of the first and second sets has a tensile strength of from about 15 ksi to about 120 ksi, a tensile modulus of from about 200,000 psi to about 2,000,000 psi, and an average thickness of from about 0.15 mm to about 0.6 mm.

37. The endoprosthesis of claim 34 wherein:

the prosthesis structure is radially constrained to about half of said annealed diameter D whereby the predetermined fraction is one-half, and the radial force RF exerted in grams, as a function of the annealed diamater D in mm, is defined by the equation RF=−15D+491+20.

38. The endoprosthesis of claim 34 wherein:

the filaments include at least one of polydioxanone, polycaprolactone, polygluconate, polylactic acid-polyethylene oxide copolymers, modified cellulose, collagen, poly(hydroxybutyrate), polyanhydride, polyphosphoester, poly(amino acids) and combinations thereof.

39. Endoprosthesis of claim 34 wherein:

the first and second common directions of winding are opposite one another.

* * * * *

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Jonathan Stinson**
Application No.:	**10/037036**
Filed:	**October 25, 2001**
For:	**Balloon Expandable Polymer Stent With Reduced Elastic Recoil**
Group Art Unit:	**3731**

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2B-9919-US01

BRIEF ON APPEAL

This is a Brief on Appeal for the above-identified application in which claims 1-23 were finally rejected in an Office Action mailed October 5, 2004. A Notice of Appeal was filed in this case on December 17, 2004. This brief is submitted in accordance with 37 C.F.R. § 41.37:

> *(a)(1) Appellant must file a brief under this section within two months from the date of filing the notice of appeal under §41.31.*
>
> *(2) The brief must be accompanied by the fee set forth in §41.20(b)(2).*
>
> *(b) On failure to file the brief, accompanied by the requisite fee, within the period specified in paragraph (a) of this section, the appeal will stand dismissed.*

The fees required under § 41.20(b)(2) and any required petition for extension of time for filing this brief therefor are dealt with in the accompanying Transmittal Letter.

> *(c)(1) The brief shall contain the following items under appropriate headings and in the order indicated in paragraphs (c)(1)(i) through (c)(1)(x) of this section, except that a brief filed by an appellant who is not represented by a registered practitioner need only substantially comply with paragraphs (c)(1)(i) through (c)(1)(iv) and (c)(1)(vii) through (c)(1)(x) of this section:*

(i) Real Party in Interest

> *(i) Real party in interest. A statement identifying by name the real party in interest.*

The application is assigned to Boston Scientific Scimed, Inc., (former name: Scimed Life Systems, Inc.), SciMed Life Systems, Inc., One SciMed Place, Maple Grove, MN

55311-1566, a Minnesota Corporation and a subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts, 01760-1537, a Delaware Corporation.

(ii) Related Appeals and Interferences

(ii) Related appeals and interferences. A statement identifying by application, patent, appeal or interference number all other prior and pending appeals, interferences or judicial proceedings known to appellant, the appellant's legal representative, or assignee which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal. Copies of any decisions rendered by a court or the Board in any proceeding identified under this paragraph must be included in an appendix as required by paragraph (c)(1)(x) of this section.

No related appeals or interferences are pending.

(iii) Status of claims

(iii) Status of claims. A statement of the status of all the claims in the proceeding (e.g., rejected, allowed or confirmed, withdrawn, objected to, canceled) and an identification of those claims that are being appealed.

Claims 1-23 are pending and have been rejected. No claims have been allowed, withdrawn, objected to or cancelled. The claims that are being appealed are 1-23.

(iv) Status of amendments

(iv) Status of amendments. A statement of the status of any amendment filed subsequent to final rejection.

No amendment was filed subsequent to final rejection.

(v) Summary of claimed subject matter

(v) Summary of claimed subject matter. A concise explanation of the subject matter defined in each of the independent claims involved in the appeal, which shall refer to the specification by page and line number, and to the drawing, if any, by reference characters. For each independent claim involved in the appeal and for each dependent claim argued separately under the provisions of paragraph (c)(1)(vii) of this section, every means plus function and step plus function as permitted by 35 U.S.C. 112, sixth paragraph, must be identified and the structure, material, or acts described in the specification as corresponding to each claimed function must be set forth with reference to the specification by page and line number, and to the drawing, if any, by reference characters.

Claims 1-23 pertain to processes for forming medical devices from polymer materials, especially polymer stents, and to medical devices produced thereby. The required

references to the specification and drawings are provided in brackets in the claim summaries below.

The invention provides a novel technique by which the molecular orientation of a formed polymer stent or a tubular stent preform can be improved to increase hoop-wise orientation. The process is particularly suited to balloon expandable polymer stents. Such stents typically have suffered from high elastic recoil after release of balloon inflation pressure [p. 4, ln.14-23].

According to independent claim 1, a generally tubular stent of the polymer material is formed [p.5, lines 7-9; Fig.1; p. 8, ln.1-10]. Examples of how this step may be done include molding, welding a pattern-cut sheet, and cutting or etching a pattern into a cylindrical tube.

The formed stent is then radially expanded to produce an expanded diameter stent [p.5, ln. 10-20; Fig. 2]. Examples of how this may be done include using an expanding mandrel or collet, sliding over a tapered mandrel, and expansion with a balloon. The purpose of this step is to cause the molecular structure of the polymer to orient itself around the hoop, stretching causing molecular alignment in the direction of the elongation and increasing strength in the direction of orientation [p.8, ln.22-29]

Then, the expanded diameter stent is annealed to shrink its diameter to a reduced diameter [p.5, ln. 21-25; Fig.3]. The purpose of the annealing step is to reduce or eliminate residual elastic stresses and to shrink the stent to size for deployment [p.9, ln.15-21].

According to dependent claim 2, the steps of radially expanding the stent and of annealing the expanded diameter stent are repeated at least once in sequence [p.5, ln.25-27]. The annealing step causes some loss of orientation. Repetition of the radial expansion and annealing steps improves final molecular orientation by an incremental additive mechanism. [p. 9, ln.19-25].

According to dependent claim 3 the stent is formed by molding the polymer material [p. 8, ln.1].

According to dependent claim 9 the step of radially expanding the stent is performed at room temperature [p.5, ln. 12-14].

In dependent claim12, a thermoplastic polymer stent having a molecular orientation as obtained by a process as in claim 1 is claimed. [p.5, ln.28 - p.6, ln.2; Figs 3-5; p. 9, ln. 1-7; Fig. 7]. In independent claim 13 a thermoplastic polymer stent having a hoopwise molecular orientation is claimed.

In independent claims 15, 17 and 21 the radial expansion and annealing steps are performed on a tubular article [p. 11, ln.23 - p. 12, ln. 9]. According to claim 15, the radial expansion and annealing steps are repeated at least once in sequence [p. 12, ln.5]. According to claim 17 the polymer material is biodegradable [p.12, ln.5-6]. According to claim 21, after the annealing step (c) a stent form is fashioned from the tube [p. 12, ln. 69].

(vi) Grounds of Rejection to be Reviewed on Appeal

(vi) Grounds of rejection to be reviewed on appeal. A concise statement of each ground of rejection presented for review.

Review on appeal is requested of the Examiner's contention that Stinson (US 6,245,103), a commonly owned prior patent of the present inventor, anticipates claims 1-23. In particular for specified claim subgroups, applicant disputes the Examiner's contentions a) that Stinson shows an annealing step performed after a radial expansion step b) that repetition of the radial expansion and annealing steps in sequence is shown in the Stinson patent; c) that the Stinson patent shows a polymer stent formed by molding or etching; e) that the Stinson patent shows a radial expansion step performed at room temperature; e) that the Stinson patent shows stents having "hoopwise" molecular orientation; and f) that Stinson patent shows a process in which a stent pattern is formed from a tube that has first been subjected to sequential radially expansion and annealing steps.

Review on appeal is also requested of the Examiner's contention that claims 1, 13, 15, 17 and 21 are obvious from Andrews et al (US 6,156,254) in view of Lennard et al (US

4,911,165). In particular applicant disputes a) that the Andrews patent shows a step of forming a stent, that Andrews has a col. 12, lines 25-28, that polypropylene filaments of Lennard et al have any relevance to the Andrews stent, and that motivation to combine the Andrews stent with Lennard sutures has been articulated. Additionally, for specified claim subgroups the applicant disputes: b) that the combination anywhere describes or suggests a process for forming a polymer stent; c) that a polymer stent, much less a polymer stent having hoopwise orientation, is taught or suggested by the combination; d) that repetition of the radial expansion and annealing steps in sequence is shown in the combination; e) that a polymer stent of biodegradable material is taught or suggested by the combination; and f) that the combination teaches or suggests a process in which a stent pattern is formed from a tube that has first been subjected to sequential radially expansion and annealing steps.

(vii) Argument

(vii) Argument. The contentions of appellant with respect to each ground of rejection presented for review in paragraph (c)(1)(vi) of this section, and the basis therefor, with citations of the statutes, regulations, authorities, and parts of the record relied on. Any arguments or authorities not included in the brief or a reply brief filed pursuant to §41.41 will be refused consideration by the Board, unless good cause is shown. Each ground of rejection must be treated under a separate heading. For each ground of rejection applying to two or more claims, the claims may be argued separately or as a group. When multiple claims subject to the same ground of rejection are argued as a group by appellant, the Board may select a single claim from the group of claims that are argued together to decide the appeal with respect to the group of claims as to the ground of rejection on the basis of the selected claim alone. Notwithstanding any other provision of this paragraph, the failure of appellant to separately argue claims which appellant has grouped together shall constitute a waiver of any argument that the Board must consider the patentability of any grouped claim separately. Any claim argued separately should be placed under a subheading identifying the claim by number. Claims argued as a group should be placed under a subheading identifying the claims by number. A statement which merely points out what a claim recites will not be considered an argument for separate patentability of the claim.

1. The Examiner Erred in rejecting claims 1-23 as anticipated by Stinson et al US 6,245,103

a. Claims 1-12 and 15-23 - Annealing of a Radially Expanded Stent or Tube

Anticipation under 35 U.S.C. Section 102(e) requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co.* , 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); *In re Robertson*, 49 USPQ2d 1949 (Fed. Cir. 1999). The Stinson patent does not anticipate any of claims 1-23.

The Examiner contends:

> Stinson discloses in figs 1, 4, 14 and table 6, a process for forming a stent having the limitations of claims 1-2, 12,15,17-18 and 21-22, including: the process comprises the step of forming a tubular stent (10) of the polymer material (see col. 16, lines 21-27); the stent radially expanding to produce an expanded diameter stent, ***annealing the expanded diameter stent that shrinks from its expanded diameter to a reduced diameter (see col. 12, lines 25-28 and col. 16, lines 27-67),*** and at least one time repeating of steps b) and c) in sequence. ***(emphasis added)***

The Examiner is clearly wrong.

The stents of the Stinson patent are polymer stents formed from polymers. The process and the products formed, however, are very different from the inventions of claims 1-23 of the present application. The Stinson stents are formed by braiding polymer fibers onto a mandrel and then annealing the braided stent onto a second mandrel of smaller diameter. After the annealing step the stent is stretched longitudinally to a further reduced diameter at which it is

delivered. Upon delivery, the stent will *self-expand* to a deployed diameter less than the annealed diameter. The difference between the braid mandrel diameter and the anneal mandrel diameter can be varied to give a desired deployed diameter with in a predetermined range. Determination of the what the deployed diameter will be for a particular stent configuration, and what the radial force at a fraction thereof will be, is described and exemplified at col. 15, ln. 40 - col. 17, ln. 9. Separate stents are used with the different anneal mandrels to provide the reference data [*see in particular* col. 17, ln. 4-9]. The data can be used to formulate linear equations that enable prediction of annealed stent diameter that will yield a target radial force value, or the deployed stent diameter from the annealed stent diameter, for a given braid design and delivery system size.

Column 12, lines 25-28 of the Stinson patent, cited by the Examiner, is irrelevant to the subject matter of the present invention. It pertains to testing done on polymer *filament* properties to determine whether annealing would significantly change strength or modulus properties of the filaments (col. 11, ln. 20-30). This is a test. There is no indication that, in a stent forming process, the filaments are to be annealed before they are braided into the stent. Moreover, even if the filaments were annealed before they were braided into stents, such a process would be irrelevant to the process of the invention which only recites annealing of the stent. The filaments used to braid the Stinson patent stents are not themselves stents or tubular medical articles. Consequently, the Examiner has clearly erred in citing col. 12, lines 25-28 of the Stinson patent to justify his anticipation rejection.

The citation of col. 16, lines 27-67 is equally inapt. This is a portion of the passage that we have already shown describes how to formulate linear equations that enable prediction of annealed stent diameter that will yield a target radial force value, or the deployed stent diameter from the annealed stent diameter, for a given braid design and delivery system size. It does not teach anything about annealing an expanded diameter stent. Annealing is performed on the stent as formed.

As recited in claim 1, the "expanded diameter stent" is the product of a radial expansion step (b) performed on the already formed stent. It is this "expanded diameter stent" that is subjected to the annealing step (c), not the stent as formed. This is made absolutely clear in step (c) both from the word "then" in the lead-in to step (c) and in step (c)'s the reference to

"the expanded diameter stent," which necessitates that we treat the product of step (b) as the starting point for step (c). This is elementary method claim language. There is nothing tricky about the proper construction of the claim language.

The stent of the Stinson patent is annealed from the stent diameter as formed, not from a "radially expanded diameter." The Stinson patent stent is not subjected to a radial expansion step until it is deployed, or in the case of the tests discussed in col. 16 when it is tested subjected to testing to determine deployed diameter and radial force. No annealing step takes place after such radial expansion. The stent of the Stinson patent is annealed before radial expansion occurs. The Stinson patent sequence described at col. 5, lines 31-39:

> ... make the stent at a particular diameter (A), anneal the stent at a smaller diameter (B), and deploy the stent from a delivery system of diameter (C) whereby the stent will be "programmed" to self-expand to a desired implant diameter (D). The relationship between the diameters is A>B>D>C.

In this sequence diameter D is the only diameter that is achieved by a radial expansion step and hence the only "radially expanded" diameter. Diameter D is achieved after the annealing step has been performed. Therefore the Stinson patent does not anticipate the process of claim 1 and its dependents.

A parallel construction applies to the article forming steps of independent claims 15, 17 and 21. Therefore the Stinson patent does not anticipate these claims or their dependents.

At least for the reasons just given the anticipation rejection of claims 1-23 should be reversed.

b. Claims 2, 15-16, 18, and 22 - Repetition of the Radial Expansion and Annealing Steps in Sequence

Claims 2, 15-16, 18, and 22 require repetition of steps (b) and (c) at least one time in sequence. The Examiner contends that the same passages of the Stinson patent show this. The applicant has no idea what the Examiner is thinking. The Stinson patent does not show repetition of radial expansion and subsequent annealing steps on a formed stent.

c. Claims 3 and 23 - Polymer Stent Formed By Molding or Etching

"Regarding claims 3 and 23," the Examiner asserts in the Final Action, "Stinson discloses the stent is formed by molding or etching the polymer material (see col. 1, lines 43-66). Once again, the Examiner is clearly wrong.

Column 1, lines 43-66, of the Stinson patent is in the Background section of the patent and pertains to metal stents, not polymer material stents. No mention of molding or etching, much less of molding or etching a polymer stent, is found in this location. The polymer stents of the Stinson patent are made by braiding polymer filaments, not by molding.

d. Claim 9 - Radial Expansion Step Performed At Room Temperature

"Regarding claims 8-9," the Examiner asserts in the Final Action, "Stinson discloses the process has a temperature that is below the glass transition temperature of the polymer material; and wherein the step b) performs at room temperature (see col. 19, lines 22-50)."

The Stinson patent does not show a radial expansion step at the cited location. A stent is formed on a braid mandrel, annealed at a temperature between glass transition temperature and melting temperature of the polymer material, and then cooled to room temperature. Cooling to room temperature after annealing is not radially expanding the stent at room temperature before annealing.

e. Claims 12-14 "Hoopwise" Molecular Orientation

"Regarding claims 13-14," the Examiner asserts in the Final Action, "Stinson discloses the stent has a hoop or circular orientation (see figs 1); and wherein the polymer is biodegradeable (see col. 2, lines 7-60)."

Claim 13 recites a thermoplastic polymer stent having a "hoopwise molecular orientation." Claim 14 depends from claim 13.

The hoopwise molecular orientation is substantially circular, as shown in Fig. 7 and discussed at page 8, line 22 - page 9, line 5. The Stinson patent stents are formed from longitudinally oriented fibers wound in a helical braid of crossing fibers. The orientation is not substantially circular. Even assuming that the molecular orientation in the Stinson patent stent follows the longitudinal axis of the fibers, there is a substantial longitudinal component to each

fiber winding. For this reason the Stinson patent does not disclose a stent which anticipates claim 13 or claim 14 which depends therefrom.

Because the process of claim 1 changes the molecular orientation of a stent toward a hoopwise orientation, the product of that process, recited in claim 12 is also seen to be patentably distinguished from the Stinson patent stents.

f. Claims 21-23 - Stent Pattern Formed From a Tube That Has First Been Subjected To Sequential Radially Expansion and Annealing Steps

Independent claim 21 recites a process for forming a polymer stent which also includes sequence recitations. In claim 21 a polymer tube is formed, radially expanded, ***the radially expanded tube*** is annealed, ***and subsequently*** the stent is formed ***from the annealed tube***. That is, the stent pattern is provided ***after*** the tube has been both b) radially expanded and c) annealed at least one time. This may be accomplished, for instance, by machining or etching the tube after the steps b) and c) have been performed.

In the braided stent of the Stinson patent, tube formation and stent pattern formation are the same step, *i.e.* braiding the tube over a mandrel. There is no teaching or suggestion of the process sequence as recited in claim 21.

2. The Examiner Erred in rejecting Claims 1, 13, 15, 17 and 21 as Obvious over Andrews et al US 6156254 in view of Lennard et al US 4,911,165

Claims 1, 13, 15, 17 and 21 have been rejected under 35 USC 103 (a) over Andrews et al. (US 6,156,254) in view of Lennard et al (US 4,911,165). The rejection must be reversed.

a. Claims 1, 13, 15, 17 and 21 - Misconstruction of References, Confusing Assertions, Absence of Motivation

To support an obviousness rejection, the cited prior art must specifically suggest the combination as claimed, and it must be applied in the context of their significance to a technician at the time the invention was made, without knowledge of the solution. It is impermissible, simply to engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template, picking and choosing among isolated disclosures in the

various documents to supply elements to fill the gaps. The cited documents themselves must provide some teaching whereby the applicant's combination would have been obvious, again at the time the invention was made. US patent law is replete with cases that illustrate this principle. *See e.g. In re Fine,* 37 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988); *In re Oetiker*, 24 USPQ2d 1443, 1446 (Fed. Cir. 1992); *In re Fritch*, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992); *In re Kotzab,* 55 USPQ2d 1313, 1316 (Fed. Cir. 2000); and *In re Dembiczak*, 50 USPQ2d 1614 (Fed. Cir.1999). The Examiner has not made the requisite showing.

The Examiner begins the explanation of the rejection on pages 3-4 of the Final Office Action as follows:

> Andrews et al show in fig. 10, a process having all the limitations of claims 1, 13, 15, 17 and 21, including: the step of forming a tubular stent (10); the stent radially expands to produce an expanded diameter stent. However, Andrews et al do not disclose the step of annealing the expanded diameter stent that shrinks its diameter to a reduced diameter (see col. 12, lines 25-28).

This is not correct.

Andrews et al shows a stent in Fig 10 "which is a coil of stainless steel" (col. 9 lines 19-24). Stainless steel is metal. Claims 1, 13, 15, 17 and 21 all pertain to processes or articles made of polymer, not metal. The Andrews et al stent is irrelevant to the present application. A skilled person will not look to this document to find a polymer stent or a process for forming a polymer stent. .

Even if the stainless steel stent of Andrews et al were relevant to the application, it does not show a step of forming a tubular stent as asserted in the Office Action. Andrews et al pertains to a balloon formation process, not to a stent formation process. It teaches ***nothing*** about forming the stainless steel coil stent of Figure 10.

The Final Office Action fails to indicate how the sequence recited in claims 1, 15, 17 or 21 are believed to be taught or suggested by Andrews et al. No such teaching exists.

The Final Office Action refers to "col. 12, lines 25-28." There is no such location. The Andrews et al patent ends at the bottom of column 10.

Continuing with the explanation of the rejection, the Examiner states on page 4 of the Final Office Action:

> Lennard et al teach using polypropylene filaments then annealed in an oven and allowed to shrink from about certain percent of the original length (see col. 4, lines 55-65).
>
> It would have been obvious to one having ordinary skill in the art at the same time the invention was made to modify Andrews et al by adding polypropylene filaments then annealed in an oven and allowed to shrink as taught by Lennard et al et al in order to reduce the initial stretching and to allow the material to become constricted from heat or cold temperature. Furthermore, it will increase the final molecular orientation of the stent.

This is not understood.

Lennard et al pertains to surgical filament sutures. It doesn't pertain to stents at all, much less to polymer stents. How is the examiner proposing to accomplish "adding" the filaments? Are the polypropylene fibers being used in some way as sutures? If not, why are suture filaments being used? Are they being used to form part of the Andrews et al stainless steel stent? If so what part?

The statement "in order to reduce the initial stretching and to allow the material to become constricted from heat or cold temperature," is understood to be an assertion of a motivation for the combination, but it is not understood what "initial stretching" is being referred to. Andrews et al doesn't describe an initial stretching of the Fig. 10 stent. Likewise what does "becoming constricted from heat or cold temperature" have anything to do with the Andrews et al stent? In Fig. 10 of Andrews et al, the stent is being implanted in the body where it is presumably at human body temperature. Still further, in what way will the addition of annealed polypropylene fibers increase the final molecular orientation of a stainless steel stent?

All of these problems with the rejection as articulated by the Examiner were raised in response to the first Action in this application. None of them have been addressed in the Final Action. The Examiner simply repeated the initial rejection verbatim.

Furthermore, the applicant does not understand the phrase "then annealed in an oven," and does not see how it relates to performing an annealing step after radial expansion of a stent or tube.

In any case, as we have noted with respect to the Stinson patent, use of annealed fibers to form a stent is irrelevant to the annealing steps recited in the various process claims.

The Examiner has not identified a reasonable motivation to combine the Andrews et al and Lennard et al patents and has not shown how any combination of teachings in these documents could produce the invention of any of claims 1, 13, 15, 17 and 21 Reversal of the rejection under 35 USC §103 is therefore respectfully requested.

b. Claims 1, 15, 17, and 21 - Annealing Sequence

Claims 15 and 17 pertain to processes for forming tubular articles, as to which Andrews et al's balloon forming process might be of interest. However, the steps of that balloon forming process are very different. In Andrews et al a composite tube is formed [col. 8, ln. 6-26, Fig. 1], stretched to a ***reduced diameter*** [col. 8, ln 27-33; Fig. 3], the ends are then heated [col. 8, ln. 34-46], after which the material is cooled and stretching is released to allow the tube to return to its original diameter, except for the ends that had been heated [col. 8, ln 47-56, Fig 5].

In claims 15 and 17, and in the stent forming process claims 1 and 21 as well, the annealing steps are all performed in a sequence and occur after a ***radial expansion*** of a formed stent or a formed tube. To the extent that end heating step of Andrews et al is considered an annealing step, it follows a ***radial reduction*** step. The Andrews sequence for balloon formation therefore cannot be considered to render obvious the processes of claims 15 or 17, much less of claims 1 and 21.

c. Claims 1 and 21 - Polymer Stent Forming Process

Claims 1 and 21 pertain specifically to processes for forming polymer stents. Since neither Andrews et al nor Lennard et al describe stent forming process, much less a polymer stent formation process, these claims cannot be rendered obvious by the combination, even if such a combination was properly motivated.

d. Claim 13 - Polymer Stent

Because the only mention of a stent in either patent is a metal stent, claim 13, which is directed to a polymer stent, is also not *prima facie* obvious. Moreover, claim 13 also recites that material has hoopwise molecular orientation. Since neither Andrews et al nor Lennard et al show a polymer stent, hoopwise orientation of such a stent cannot be obvious therefrom.

e. Claim 15 - Repetition of the Radial Expansion and Annealing Steps in Sequence

As previously described, Claim15 requires repetition of steps (b) and (c) at least one time in sequence. The Examiner has not shown where this feature can be found in the Andrews et al or Lennard et al.

f. Claim 17 - Biodegradable Material

Claim 17 recites a process for forming a tubular article in which the polymer material is biodegradable. Andrews pertains to formation of balloons, the disclosed materials of which (PET and polyurethane) are not considered biodegradable, and illustrates use with a stainless steel stent, also not biodegradable. Lennard et al describes a process for forming polypropylene sutures. Polypropylene sutures resist breakdown, have minimal reaction with tissue, and maintain strength in vivo over extended periods [Lennard et al, col, 1, ln. 16-24], all identified by Lennard as advantages of the material. The skilled person would not consider the Lennard et al to teach or suggest use of a biodegradable polymer material for sutures, much less in a process for forming a tubular article.

f. Claim 21- Stent Pattern Formed From a Tube That Has First Been Subjected To Sequential Radially Expansion and Annealing Steps

As previously described, in claim 21 a polymer tube is formed, radially expanded, the radially expanded tube is annealed, and subsequently the stent is formed from the annealed tube. That is, the stent pattern is provided ***after*** the tube has been both b) radially expanded and c) annealed. Neither Andrews et al nor Lennard et al show a process for forming polymer stent, much one in which the stent is formed from a tube after it had been radially expanded and then annealed.

3. Conclusion

The Examiner has made numerous mistakes in characterizing the disclosures of the Stinson, Andrews et al and Lennard et al patents. Claims 1-23 are not anticipated by the Stinson patent. The Examiner has not shown a motivation to combine the Andrews et al patent and the Lennard et al patents and when combined, the teachings of those patents still fail to teach or suggest the subject matter of any of claims 1-23. Claims 1-23 therefore are not obvious from

Andrews et al taken with Lennard et al. The Board is respectfully requested to reverse the rejections with instruction to pass the application to issue.

Respectfully submitted,

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(viii) Claims Appendix

(viii) Claims appendix. An appendix containing a copy of the claims involved in the appeal.

1. (Previously Presented) A process for forming a stent of a polymer material, the process comprising the steps of:

a) forming a generally tubular stent of said polymer material;

b) radially expanding the stent to produce an expanded diameter stent; and then,

c) annealing the expanded diameter stent to shrink its diameter to a reduced diameter.

2. (Original) A process as in claim 1 further comprising at least one time repeating steps b) and c) in sequence.

3. (Original) A process as in claim 1 wherein in step a) the stent is formed by molding the polymer material.

4. (Original) A process as in claim 3 wherein the polymer material is thermoplastic.

5. (Original) A process as in claim 4 wherein the polymer material is biodegradable.

6. (Original) A process as in claim 1 wherein the polymer material is selected from the group consisting of poly(alpha-hydroxy acid), polylactic acid-polyethylene oxide copolymers; modified cellulose; collagen or other connective proteins; adhesive proteins; hyaluronic acid; polyanhydrides; polyphosphoesters; poly(amino acids); copolymers thereof; and mixtures of any of said materials.

7. (Original) A process as in claim 6 wherein the polymer material is a poly(alpha-hydroxy acid) selected from the group consisting of homopolymers and copolymers of polylactide (PLA), poly-L-lactide (PLLA), poly-D-lactide (PDLA), polyglycolide (PGA), polydioxanone, polycaprolactone, poly(hydroxybutyrate), polygluconate, and mixtures thereof.

8. (Original) A process as in claim 1 wherein the step b) is performed at a temperature below the glass transition temperature of the polymer material.

9. (Original) A process as in claim 8 wherein the step b) is performed at room temperature.

10. (Original) A process as in claim 1 wherein the step c) is performed at a temperature above the glass transition temperature of the polymer material.

11. (Original) A process as in claim 10 wherein the step c) is performed at a temperature within the range of about 90□C to about 150□C.

12. (Original) A thermoplastic polymer stent having a molecular orientation as obtained by a process as in claim 1.

13. (Original) A thermoplastic polymer stent having a hoopwise molecular orientation.

14. (Original) A stent as in claim 13 wherein the thermoplastic polymer is biodegradeable.

15. (Original) A process for forming a tubular article of a polymeric material, the process comprising the steps of:

a) forming a generally tubular article of said polymeric material;

b) radially expanding the article to produce an expanded diameter article; and then,

c) annealing the expanded diameter article to shrink its diameter to a reduced diameter.

and wherein at least one time steps b) and c) are repeated in sequence.

16. (Original) A medical device adapted for body lumen navigation and/or treatment produced by the process of claim 15.

17. (Original) A process for forming a tubular article of a polymeric material, the process comprising the steps of:

a) forming a generally tubular article of said polymeric material;

b) radially expanding the article to produce an expanded diameter article; and then,

c) annealing the expanded diameter article to shrink its diameter to a reduced diameter and wherein the polymer material is a biodegradable polymer.

18. (Original) A process as in claim 17 wherein at least one time steps b) and c) are repeated in sequence.

19. (Original) A process as in claim 17 wherein the polymer material is selected from the group consisting of poly(alpha-hydroxy acid), polylactic acid-polyethylene oxide copolymers; modified cellulose; collagen or other connective proteins; adhesive proteins; hyaluronic acid; polyanhydrides; polyphosphoesters; poly(amino acids); copolymers thereof; and mixtures of any of said materials.

20. (Original) A medical device adapted for body lumen navigation and/or treatment produced by the process of claim 17.

21. (Original) A process for forming a stent of a polymeric material, the process comprising the steps of:

a) forming a tube of said polymeric material;

b) radially expanding the tube to produce an expanded diameter tube;

c) annealing the expanded diameter tube to shrink its diameter to a reduced diameter; and subsequently

d) forming a stent from the annealed tube.

22. (Original) A process as in claim 21 wherein the steps b) and c) are repeated at least once before step d) is performed.

23. (Original) A process as in claim 21 wherein in step d) the stent is formed by machining or etching the reduced diameter tube obtained from step c).

(ix) Evidence appendix. An appendix containing copies of any evidence submitted pursuant to §§1.130, 1.131, or 1.132 of this title or of any other evidence entered by the examiner and relied upon by appellant in the appeal, along with a statement setting forth where in the record that evidence was entered in the record by the examiner. Reference to unentered evidence is not permitted in the brief. See §41.33 for treatment of evidence submitted after appeal. This appendix may also include copies of the evidence relied upon by the examiner as to grounds of rejection to be reviewed on appeal.

Not applicable

(x) Related proceedings appendix. An appendix containing copies of decisions rendered by a court or the Board in any proceeding identified pursuant to paragraph (c)(1)(ii) of this section.

Not applicable

(2) A brief shall not include any new or non-admitted amendment, or any new or non-admitted affidavit or other evidence. See §1.116 of this title for amendments, affidavits or other evidence filed after final action but before or on the same date of filing an appeal and §41.33 for amendments, affidavits or other evidence filed after the date of filing the appeal.

(d) If a brief is filed which does not comply with all the requirements of paragraph (c) of this section, appellant will be notified of the reasons for non-compliance and given a time period within which to file an amended brief. If appellant does not file an amended brief within the set time period, or files an amended brief which does not overcome all the reasons for non-compliance stated in the notification, the appeal will stand dismissed.

(e) The time periods set forth in this section are extendable under the provisions of §1.136 of this title for patent applications and §1.550(c) of this title for ex parte reexamination proceedings.

US005670161A

United States Patent [19]

Healy et al.

[11] **Patent Number: 5,670,161**

[45] **Date of Patent: Sep. 23, 1997**

[54] **BIODEGRADABLE STENT**

[76] Inventors: **Kevin E. Healy**, 2517 Asbury Ave., Evanston, Ill. 60201; **Gary S. Dorfman**, 11 Sea Ridge Dr., Saunderstown, R.I. 02874

[21] Appl. No.: **654,314**

[22] Filed: **May 28, 1996**

[51] **Int. Cl.**^{6} **A61F 13/00**

[52] **U.S. Cl.** **424/426**; 424/422; 604/8; 604/154; 604/281; 128/656; 128/657; 128/658; 128/898

[58] **Field of Search** 424/422, 426; 604/8, 154, 281; 128/656, 657, 659, 898

[56] **References Cited**

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Primary Examiner—Thurman K. Page
Assistant Examiner—Kathryne E. Shelborne
Attorney, Agent, or Firm—Schiff Hardin & Waite

[57] **ABSTRACT**

An expandable, biodegradable stent for use within a body lumen comprises a hollow tube made from a copolymer of L-lactide and ϵ-caprolactone that is not plastically expandable at normal body temperatures, and that is expandable using thermo-mechanical means at a temperature between about 38°–55° C. using a balloon catheter. The invention also relates to a method of making such a stent and to a method of deploying such a stent within the body.

51 Claims, 5 Drawing Sheets

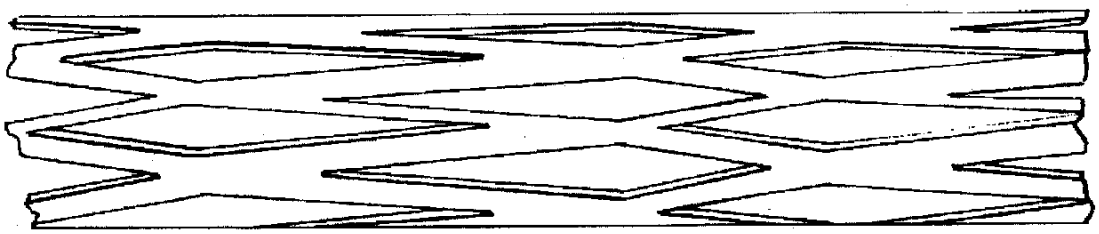


FIG. 1

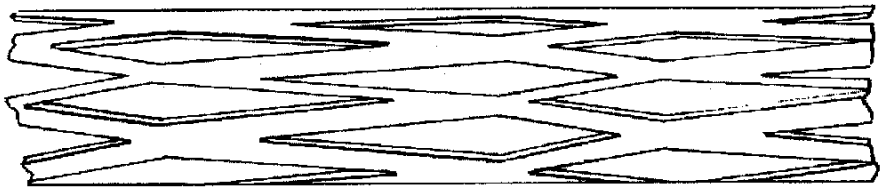


FIG. 2

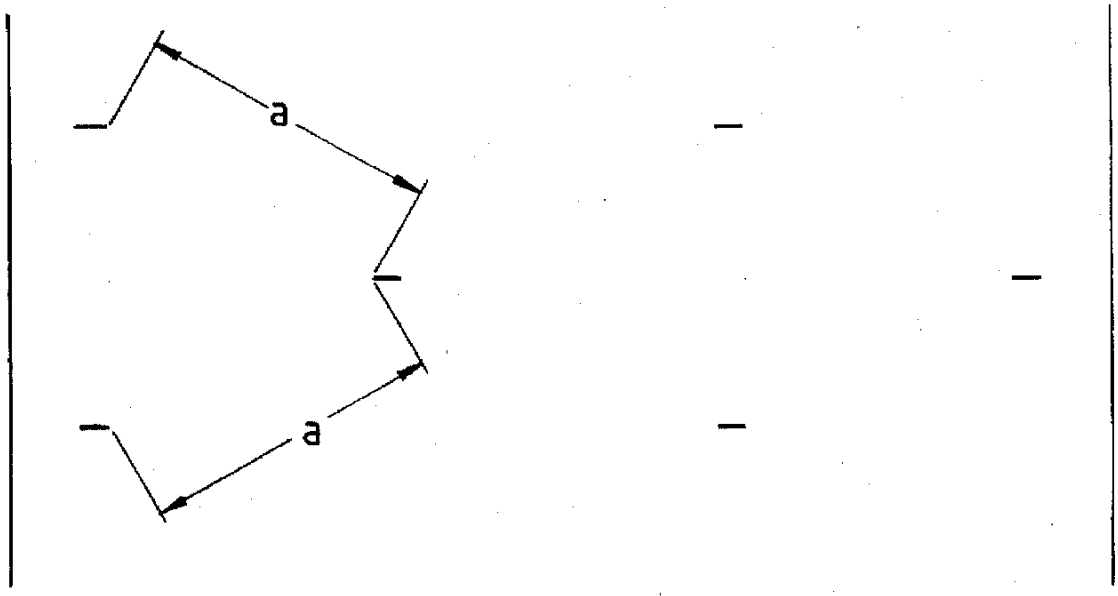


FIG. 3

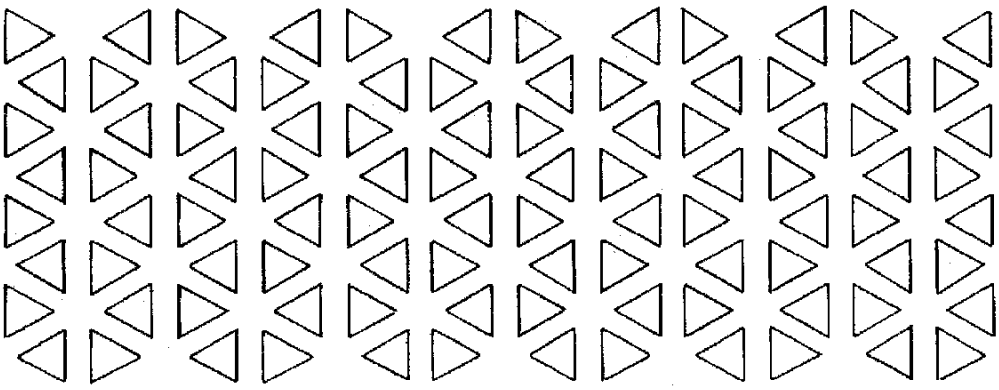


FIG. 4

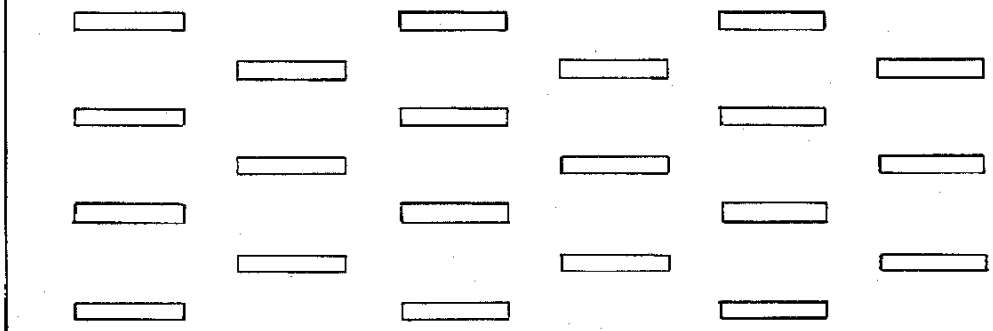
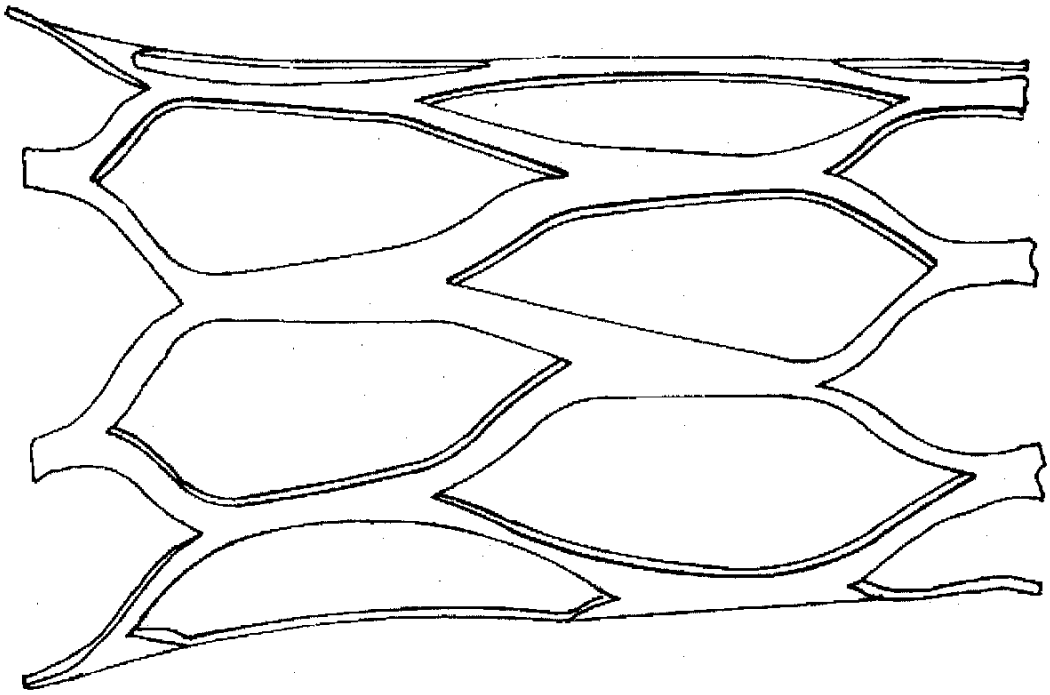


FIG. 5



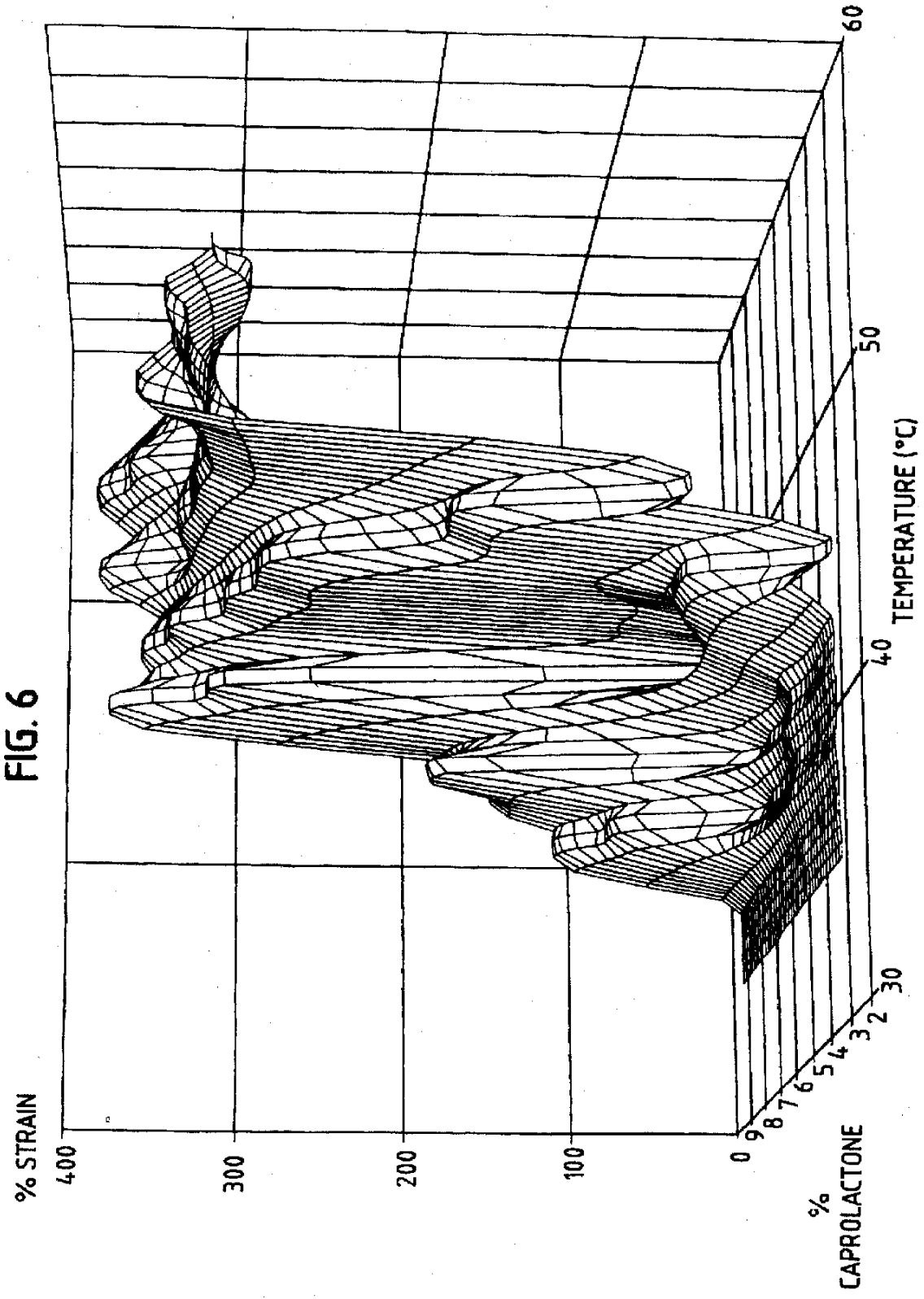

% STRAIN
400
300
200
100
0
% CAPROLACTONE
9
8
7
6
5
4
3
2
30
40
50
60
TEMPERATURE (°C)

FIG. 6

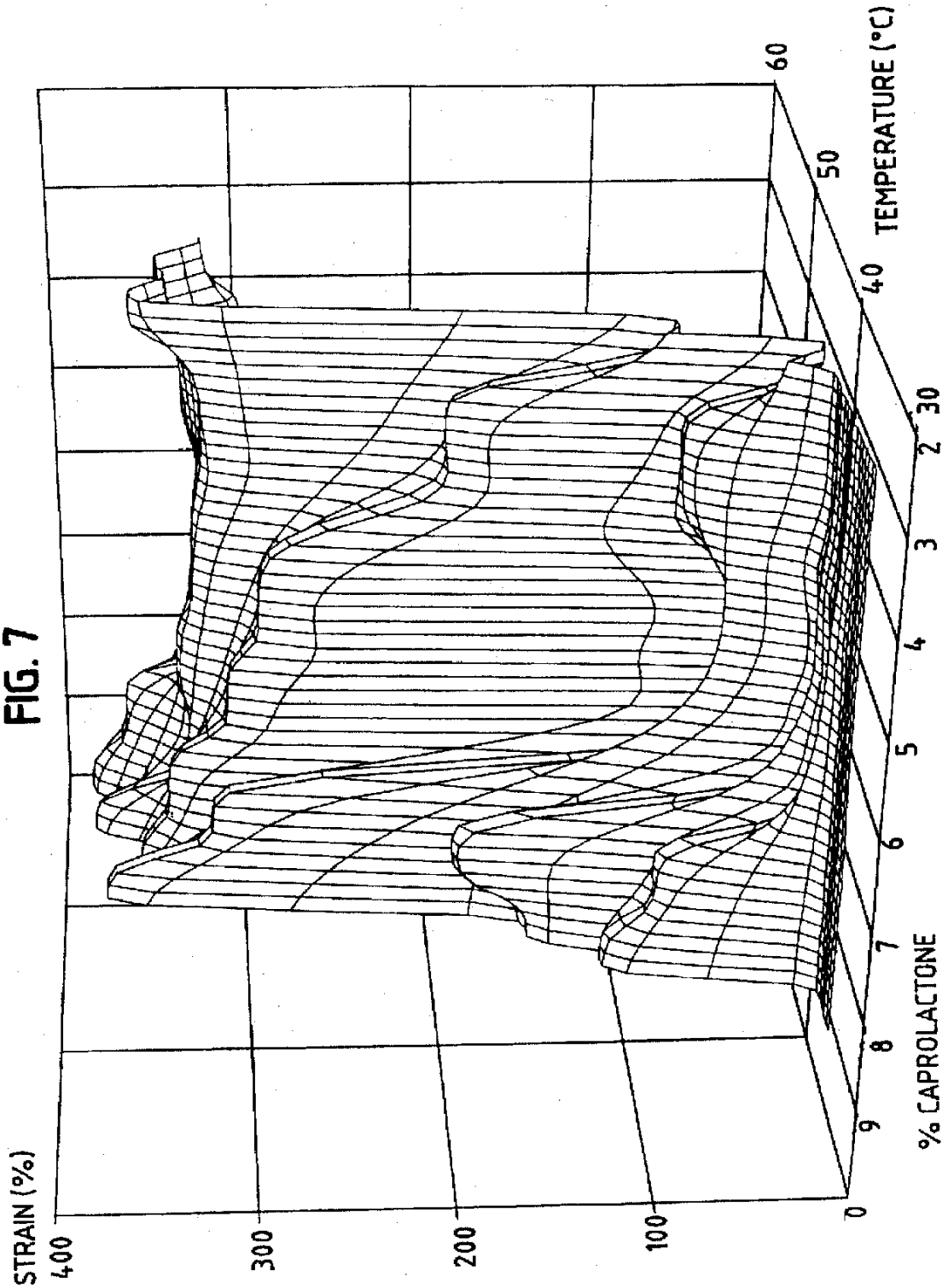

STRAIN (%)
400
300
200
100
0
% CAPROLACTONE
9
8
7
6
5
4
3
2
30
TEMPERATURE (°C)
60
50
40

FIG. 7

BIODEGRADABLE STENT

The present invention relates to a biodegradable stent that is capable of being absorbed by the human body, and that also may function as a drug or nutrient delivery system as a result of its biodegradable properties.

BACKGROUND OF THE INVENTION

Stents, including cardiovascular and biliary stents, are well-known as devices that are used to support a body lumen, such as an artery, vein, biliary duct, or esophagus. They may be employed as a primary treatment for a constriction of a body lumen (stenosis), or may be used following a medical procedure, such as angioplasty, used to remedy stenosis.

Conventional stents have taken two forms. First, there are the self-expanding stents that typically are made of metal, and that may include a biocompatible coating. Such stents are permanently implanted into the human body by deploying them on or through a catheter, although removable stents of this kind are known to the art. The stent, which may be woven, strutted, or wound like a spring, is placed in tension or compression along the inner or outer perimeter of the catheter, and percutaneously inserted into the body where it is guided to the site of implantation. The stent then is released from the perimeter of the catheter, or extruded from the interior of the catheter, where it expands to a fixed, predetermined diameter, and is held in position as a result of that expansion. Many different configurations of such self-expanding stents, and of catheters used to deploy such stents, are known to the art.

One variation on these self-expanding stents is illustrated in Kawai et al., U.S. Pat. No. 4,950,258. Kawai discloses the use of a spring-like coil of plastic having "shape memory." The stent is manufactured to a desired size from homopolymers or copolymers of lactide and/or glycolide, and then compressed under suitable conditions for insertion into the body. Thereafter, the stent is heated, and because of "shape memory," returns to its original (uncompressed) size.

A second type of stent commonly used in the field is expandable as a result of mechanical action by the surgeon. One such stent is disclosed in Palmaz, U.S. Pat. Nos. 4,733,665, 4,776,337 and 4,639,632. According to the Palmaz patents, an unexpanded stent is permanently implanted in the body by percutaneously inserting it into a vessel using a catheter, and guiding the stent to the site where it is to be permanently implanted. Upon reaching the site of implantation, the balloon portion of the catheter is expanded, and concomitantly a portion of the stent also is expanded solely as a result of the mechanical force applied by the expanding balloon, until the stent is sized appropriately for the implantation site. Thereafter, the expanded balloon is deflated, and the catheter is removed from the body, leaving the stent held permanently in position. The stents disclosed in Palmaz are made of a metal or a nondegradable plastic, and, to achieve compatibility with and in the body, the stent may be coated with a biologically-compatible substance.

Commercially available stents of the types described above exhibit undesirable characteristics that the art has sought to overcome. Self-expanding stents may be inappropriately sized for the sites where they are to be deployed, increasing the risk of rupture, stent migration, stenosis, and thrombosis as the stent continually tries to expand after deployment to its predetermined, optimal diameter. Conversely, a stent sized too small for the lumen may project into the lumen, thereby causing a primary or secondary

obstruction or migration. Both self-expanding and expandable stents that are known in the art, because they are designed for permanent implantation in the body, increase the risk of restenosis, thrombosis or other adverse medical effects because of the risk of adverse reaction by surrounding tissue, adverse reaction by the material flowing through the body lumen (such as blood or blood products), and deterioration of surrounding tissue and/or the stent itself. The metals or alloys used for such stents, because they are believed to be biologically stable, also remain in the body for the patient's life, unless surgically removed at a later date along with surrounding tissue. Thus, these stents do not permit temporary placement within the body unless patient and surgeon are prepared to undertake a second procedure to remove the stent, which is difficult or impossible in most cases.

Conventional balloon-deployed stents, like that described by Palmaz, also require an extensively perforated structure that can be mechanically expanded intraluminally by a balloon catheter without applying forces that are potentially threatening to the surrounding tissue. Such perforations also permit cell growth to occur from the intima or media lining the lumen. Thus, for example, endothelial cells and smooth muscle fibroblasts migrate through the perforations inside and around stents like that shown in Palmaz. Such endothelial cell growth is desirable to the extent that the endothelial layer inhibits the formation of blood clots (thrombogenesis) by providing a blood-compatible surface. However, vascular smooth muscle cell migration and proliferation may be undesirable when it is uncontrolled (as in intimal hyperplasia) and results in the occlusion of the lumen that has been surgically opened by placement of the stent. Thus, stents such as that described by Palmaz may be undesirable when the risk of intimal hyperplasia is substantial. The benefits of a balloon-deployed stent therefore may not be realized in such circumstances. Moreover, to the extent that the design of stents such as those described in Palmaz are dictated primarily by mechanical considerations, such as the forces needed to open the stent, biological considerations (such as designing the stent to limit cell ingrowth and migration, for example) frequently play a secondary role or no role at all.

Still another disadvantage of existing stents is that the materials from which they are made are rigid, and therefore the compliance of the stents (i.e., the ability to control the flexibility of the material used to design stents for particular applications) is limited. This has the disadvantage of exposing patients to risks associated with the placement of a device that may exhibit a rigidity in excess of that needed for the particular application.

Most conventional stents also are capable of being used as drug delivery systems when they are coated with a biodegradable coating that contains the drug to be delivered. The amount of the drug that can be delivered, and the time over which it may be released, therefore may be limited by the quantity of coating employed.

Beck et al., U.S. Pat. No. 5,147,385, discloses the use of a degradable, mechanically expandable stent prepared from poly(ε-caprolactone) or similar polymers that melt between 45°–75° C., because the melted polymer may be expanded in such a manner as to adapt to the body lumen in which it is deployed. At the same time, because poly(ε-caprolactone) enters a liquid phase in the temperature range that Beck discloses (at about 60° C.), the ability to achieve controlled, improved strength characteristics using the stent described by Beck is limited. Furthermore, the temperature range described by Beck et al. is well-above the glass-transition

temperature for poly(ϵ-caprolactone). This limits the ability of a stent made according to Beck et al. to resist radially compressive forces imparted by the lumen upon the stent without creeping or relaxing, introducing a substantial risk of occluding the lumen. Alternatively, one might use massive structures made according to Beck et al. to keep the lumen open, but in so doing, the normal function of the lumen would be perturbed significantly, possibly creating regions where flow of body liquids through the lumen would be severely restricted or stagnate, so that clots may form in those regions.

Slepian et al., U.S. Pat. No. 5,213,580, discloses an endoluminal sealing process using a poly(caprolactone) material that is flowable at temperatures above 60°–80° C. According to Slepian, this flowable material is able to conform to irregularities on the inner surface of the body lumen in which it is deployed.

Goldberg et at., U.S. Pat. No. 5,085,629, discloses the manufacture of a urethral stent made from a terpolymer of L-lactide, glycolide, and ϵ-caprolactone, which is selected to permit the stent to degrade within the body. Goldberg does not, however, disclose the use of an expandable stent, nor does Goldberg et al. provide any information regarding the design of the stent or its method of deployment within the body.

Thus, a stent that overcomes the problems just identified, while at the same time providing or enhancing the benefits that result from the use of stents, is needed to improve patient safety and recovery.

SUMMARY OF THE INVENTION

The present invention seeks to overcome those problems by providing an expandable, biodegradable stent for use within a body lumen. The invention consists in essence of a hollow tube made from a copolymer of L-lactide and ϵ-caprolactone that, in unexpanded form, is of a first diameter sufficient to be retained upon a balloon catheter for placement within the body lumen. The stent is not expandable at normal body temperatures. The stent is expandable using a thermally-assisted mechanical expansion process at a temperature between about 38°–55° C., to a second diameter sufficiently large to be retained in place within the body lumen. The invention also is found in a method of making that stent, and in a method of deploying such a stent within the body.

It is thus an object of the invention to provide a biodegradable stent that can be deployed in the body for a sufficient period of time to permit the site to be supported by the stent to heal, remodel, and grow strong, and thereafter to be absorbed into the body, thus reducing the risk of thrombosis or other adverse health effects associated with foreign materials in the body.

It is still another object of the invention to provide such a stent which can be deployed percutaneously by taking advantage of thermally-activated properties that permit the stent to be permanently deformed at temperatures just above normal body temperature, while remaining sufficiently rigid at body temperature to provide for mechanical support of the surrounding tissue.

Another object of the invention is to provide a stent that can be designed with a variable geometry and compliance to permit the designer and/or surgeon to tailor the characteristics of a particular stent to fit its application more precisely than is presently possible.

Still another object of the invention is to provide such a stent made from a material that permits the use of the stent as a drug delivery system to promote healing at the site of deployment. These and other objects of the invention are achieved as described below.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an illustration of an embodiment of an unexpanded stent according to the present invention.

FIGS. **2–4** are plan drawings of various perforation patterns useful for stents made according to the invention.

FIG. **5** is an illustration of the end portion of the stent of FIG. **1** after expansion.

FIGS. **6A** and **6B** are graphs showing the relationship between caprolactone content in the copolymer of the present invention, temperature, and strain.

DETAILED DESCRIPTION OF THE INVENTION

The stent made according to the present invention comprises a cylindrical tube of appropriate size to be inserted into a body lumen, and thus typically is about 1–12 cm in length (and for vascular applications, most frequently 2–3 cm in length), and about 0.5–8 mm in diameter (for vascular stents, most frequently 1–3 mm in diameter). As shown in FIG. **1**, the stent is a hollow tube of substantial length that is used to line the body lumen and provide support for keeping the lumen open, while at the same time limiting intimal hyperplasia by providing a finite number of perforations through which cells may migrate and occlude the body lumen in the region of the stent. This technique, which includes endoluminal paving, therefore is believed to be effective in limiting intimal hyperplasia.

Endothelial coverage, in which the cells grow over and envelop the stent, is desirable in some cases because the stent may become a site for thrombosis, or clotting, to occur. As a result, it may be desirable to permit limited cell growth from the intima into the stent by providing perforations in the walls of the stent through which endothelial cells may grow and eventually cover all of the stent. Thus, as shown in FIGS. **2** through **4**, the stent made according to the present invention may desirably incorporate perforations of different size and shape to permit the ingrowth of cells from the intima. In FIG. **2**, a small perforation is provided in the walls of the stent at discrete intervals (designated by the letter "a") correlated to cell ingrowth in the particular body lumen. For example, a vascular stent having the design shown in FIG. **2** would be perforated at 2 mm intervals to accommodate cell ingrowth from the vascular intima, which has been shown to grow over this distance.

FIGS. **3** and **4** show perforation patterns that have been found desirable for expanding the stent intraluminally while maintaining significant hoop strength. Alternatively, the stent may be an imperforate tube.

Perforations in the walls of a stent made according to the present invention reduce the amount of material that must be heated to permanently deploy the stent. As a result, those perforations permit the stent to be deployed with a lesser amount of heat than if the stent were not perforated. This means that a perforated stent can be deployed using lower temperature heating devices, or with less heating time, or both, than if perforations were not present. (The stent still must be heated near or above the glass-transition temperature, as described below, to be expanded.) The size and shape of these perforations, the frequency of their placement along the walls of the stent, and the thickness of the stent material also control the total force required to

expand the stent, and also to resist collapse after deployment. The characteristics of the perforations also affect the change in length of the stent as it is expanded. Finally, such perforations may be placed to accomplish desirable biological effects, such as control ingrowth or migration, at distances that maximize the ability to prevent lumen narrowing, and that also foster cell ingrowth for the particular body lumen. The design thus may be selected to optimize the mechanical properties required of the stent with the biological properties that are desired from the stent.

In a particularly preferred embodiment of the invention, a radio-opaque contrast material is incorporated into the stent, so that the location of the stent can be determined using conventional radiographic techniques. The radio-opaque material may take the form of a platinum wire or other similar radio-opaque structure that is molded into the stent or inserted through perforations in the stent. Alternatively, the radio-opaque material may take the form of fine particles of barium sulfate that are blended with the copolymer from which the stent is made; in this case, the radio-opaque material must not adversely impact the mechanical properties of the copolymer, and must be biocompatible.

When the stent is expanded, any perforations that are included in the stent also are expanded, and their shape is changed. This is illustrated in FIG. 5, which is an expanded version of the stent depicted in FIG. 1.

Regardless of the macrostructure of the stent, the stent of the present invention is prepared from a copolymer of L-lactide and ϵ-caprolactone in the molar ratios described below. In addition to the random copolymer, blends of either this copolymer (with different quantities of L-lactide and ϵ-caprolactone in each component of the blend) or of each homopolymer also may be used to achieve the desired thermal and mechanical properties in the final product. The L-lactide-ϵ-caprolactone copolymer is biodegradable, in that it is broken down over time by random hydrolysis within the body and metabolized without adverse consequence to the patient.

The relative amounts of each of L-lactide and ϵ-caprolactone in the copolymer are selected to produce thermal and mechanical properties that permit the copolymer to be thermo-mechanically expanded just above normal body temperatures, while remaining sufficiently rigid and strong at normal body temperatures to support the body lumen. Thus, when heated, the copolymer should be expandable near its glass-transition temperature, in the range of about 38°–55° C., but the copolymer should not melt (viz., become a flowable liquid) within the temperature range. (The exact glass-transition temperature will vary depending upon the relative composition of each component of the copolymer and other physical properties of the material.) In this context, thermo-mechanical "expansion" means that the polymer can be plastically deformed without fracture by increasing the inside and outside diameters of the stent under applied heat and mechanical force. Thus, in the useful temperature range, the copolymer undergoes a transition from a glassy state, in which the copolymer is strong and stiff, and exhibits less than about 3% elongation, to a rubbery state in which the material becomes elastic, leathery, pliable, and undergoes more than about 200% elongation. It is believed that if the temperature needed to expand the copolymer is significantly higher than 55° C., the heat needed to expand the copolymer may adversely affect the surrounding tissue by burning or otherwise damaging it, thereby interfering with healing following the deployment of the stent. At the same time, however, if the expansion temperature of the polymer is below about 38° C., there is a risk that the stent will soften in the body and collapse if the temperature rises as a result of fever or other similar circumstance. This creates a risk of restenosis or other adverse conditions resulting from collapse or deformation of the softened stent.

Some mechanical properties of the poly(L-lactide-ϵ-caprolactone) copolymer are set forth in Table 1. Thus, it is believed copolymers having a molar ratio of L-lactide to ϵ-caprolactone of about 90:10 to about 98:2 (as determined by conventional NMR analysis) are useful in the present invention.

TABLE 1

L-lactide (mol %)	ϵ-caprolactone (mol %)	Melting Point (°C.)	Sample Temperature (°C.)	Modulus of Elasticity (MPa)	Strain (%)
86	14	130–140	35	1134	372
			37	878	335
			40	818	347.3
			42	338	368.7
			45	148	382.5
			47	136	384
			50	17	411.3
			53	—	393.2
91	9	141–165	35	1916	2.8
			37	1690	2.8
			40	1809	115
			42	1432	151.7
			45	758	375.2
			47	1051	356.7
			50	352	381.7
			53	121	383.3
92	8	152–171	35	1309	3
			37	910	2.9
			40	1225	88.1
			42	1451	192.5
			45	591	318.7
			47	991	340.7
			50	499	324.3
93	7	155.5*	35	1035	3.07
			37	1147	3.58
			40	1233	2.9
			42	1013	6.14
			45	1290	41.3
			47	1367	222
			50	1343	264
			53	529	294
93.5	6.5	155–172	35	1421	2.3
			37	1262	2.5
			40	1274	3
			42	1559	3
			45	1036	3.9
			47	1051	308.7
			50	543	335.7
			53	550	291.7
93.7	6.3	151.52*	35	1064	2.68
			37	1006	2.55
			40	937	2.95
			42	1104	2.73
			45	1751	38.35
			47	1128	292
			50	787	326
			53	324	319
95.6	4.4	155.44*	35	1471	2.68
			37	865	2.75
			40	788	2.83
			42	835	2.75
			45	916	74.00
			47	1192	194.00
			50	934	320.00
			53	779	330.00
			55	1572	297.00
97	3	156–178	35	1656	2.4
			37	1155	3.2
			40	1191	2.6
			42	1305	3.3

TABLE 1-continued

L-lactide (mol %)	ϵ-caprolactone (mol %)	Melting Point (°C.)	Sample Temperature (°C.)	Modulus of Elasticity (MPa)	Strain (%)
			45	1054	3.7
			47	1537	3.4
			50	1085	302
			53	1467	270.3
97.0	3.0	166.24*	35	1628	2.53
			37	1141	3.16
			40	1120	2.98
			42	1003	3.30
			45	921	3.18
			47	980	74.00
			50	1019	356.00
			53	903	342.00
			55	713	318.00

The data set forth in Table 1 were obtained by performing tensile testing in a controlled temperature environment using thin samples (approximately 0.3 mm×6.35 mm×75 mm) of the L-lactide/ϵ-caprolactone copolymer. The strain and elastic modulus data presented are averages obtained from multiple tests of each material at each temperature. Melting point data were either determined by conventional DSC techniques or modulated DSC techniques (as denoted in Table 1 by an asterisk).

FIG. 6 shows the effects of material composition and temperature on the strain of each of the materials tested. From the data plotted in FIGS. 6A and 6B, it can be seen that the material softens beginning at just above the body temperature (around 38° C.), and that pronounced strain effects can be noted in the copolymer beginning around 40° C. For the reasons noted above, the preferred copolymers exhibit the desired softening behavior beginning at a slightly higher temperature, around 43° C. The figures also reveal that softening occurs at lower temperatures in stents having a higher ϵ-caprolactone content. Thus, as shown in FIGS. 6A and 6B, at just above body temperature, copolymers having about 3–7 mol % ϵ-caprolactone exhibit a substantial improvement in elongation up to temperatures of about 55° C. However, it should be understood that copolymers containing up to about 10 mol % ϵ-caprolactone can be utilized in the invention.

Other biodegradable materials, including copolymers of L-lactide and/or ϵ-caprolactone, that exhibit similar properties also may be used in the present invention without departing therefrom.

Using the heating techniques described more fully below, the temperature of the polymer can be increased incrementally to a point near the glass-transition temperature of the copolymer, permitting the stent to enter a rubbery phase that takes advantage of a lower elastic modulus. In this phase, the stent may be plastically deformed and the shape stabilized prior to any viscoelastic behavior (such as creep, stress relaxation, strain recovery, or shrinkage) causes the stent to return to its unexpanded shape or to diminish in strength. Following expansion, the polymer is allowed to cool, but because plastic deformation has occurred, the stent remains open. Attempting to expand the stent of the present invention below the glass-transition temperature causes the stent to fracture as a result of its brittle or glassy characteristics below the glass-transition temperature. This could be potentially hazardous, depending upon whether and how the stent fractures as a result of being expanded improperly. Thus, controlled heating and expansion of the stent is important to the invention, as it results in a circumferential drawing of the extruded stent, helping to orient the copolymer molecules, and thereby enhances the modulus and strength of the materials, and ultimately the strength of the stent.

The thermo-mechanical expansion of the stent is considered a processing step occurring in situ and concomitant with deployment. Thermo-mechanical expansion can be viewed as a low temperature drawing of the copolymer tube, which orients the polymer chains and crystallites circumferentially. It is believed that this expansion method, used within the temperature range of about 38°–55° C., results in the preferential orientation of the polymer chains in the amorphous domains of the material. This low temperature drawing substantially increases the elastic modulus and strength of the stent, while stabilizing and maintaining the shape of the expanded stent under external loads. The degree of improvement of these properties depends on the draw ratio, measured as a function of the cross-sectional area of the annulus defining the end of the stent prior to and after expansion. The draw ratio should be above about 1.2, and preferably above about 2.0, and depends on the deployment method and material properties such as initial crystallinity and composition. Desirable draw ratios desired for any particular material can be readily determined by those skilled in the art.

The copolymer used in the present invention may be obtained from Purac Blochem b.v. (Gorinchem, Netherlands) in the nominal ratios specified above. However, because of the presence of unreacted monomers, low molecular weight oligomers, catalysts, and other impurities, it is desirable (and, depending upon the materials used, may be necessary) to increase the purity of the copolymer over that which is commercially available. This purification process yields a copolymer of better-known composition, and therefore increases both the predictability of the mechanical characteristics of the stents made from such materials and the reliability of those stents. In the purification process, the copolymer is dissolved in a suitable solvent, such as methylene chloride. Other suitable solvents include (but are not limited to) ethyl acetate, chloroform, and tetrahydrofuran. The copolymer solution is mixed with a second material that is miscible with the solvent, but in which the copolymer is not soluble, so that the copolymer (but not appreciable quantities of impurities or unreacted monomer) precipitates out of solution. For example, a methylene chloride solution of the copolymer may be mixed with heptane, causing the copolymer to fall out of solution. The solvent mixture then is removed from the copolymer precipitate using conventional techniques.

To form the stent, the copolymer thus prepared is melted at a temperature sufficiently low to minimize polymer degradation in a conventional extruder, and extruded through a die to form a cylindrical tube of the desired wall thickness, inside and outside diameters. The stent may be cut to length on line while hot, or preferably is cooled before cutting. The molten extrudate is cooled preferably by quenching in air or in a temperature-controlled water bath to retain shape and strength-enhancing molecular orientation (along the long axis of the tube) that is introduced by the extrusion process. The extrusion and quenching processes also are used to control the degree of crystallinity of the extruded tube, by locking in the amorphous structure of the extruded polymer, thereby reducing the glass-transition temperature to fall within the desired range. Thus, after the extrusion process, the copolymers are nearly amorphous and have oriented molecular chains.

The stents prepared in this way may be employed in the form in which they were extruded without further processing

(i.e., a solid, unperforated tube), or they may incorporate perforations of such size, shape, and frequency so as to enhance thermally-assisted mechanical expansion and allow regeneration of the vascular (or other) tissue. The perforations may be machined using excimer or other lasers, for example, a 193 nanometer argon fluoride laser which is particularly useful to take advantage of certain absorption properties of the L-lactide-ε-caprolactone copolymer. The laser pulses preferably at 40 Hz and 100 mJ/pulse, dispersing energy at 0.7 J/cm^2. The invention therefore does not rely upon a woven material to define perforations, which is an advantage because woven material potentially provides a site for thrombogenesis and bacteria colonization. In addition, deployment of woven polymer stents may be elusive, since polymers typically creep during the time when they are stored in a stressed position on the catheter.

As a alternative to the extrusion process just described, the stents may be injection molded using conventional techniques, or may be formed using dip-coating techniques. In these embodiments, any desired perforations may be part of the mold or substrate for coating, or may be micromachined as described above.

The orientation of the polymer chains and crystallites circumferentially, to improve the mechanical properties of the stent, is important. Conventional methods of processing do not allow circumferential orientation of polymer chains and crystal domains (i.e., crystallites). One method to achieve this preferred orientation is to use a glass rod with a crystal-like film of poly(tetrafluoroethylene) (PTFE) deposited mechanically on the surface by known methods. The PTFE film should be deposited circumferentially on a glass rod having an outer diameter equivalent to the desired inner diameter of the stent. The copolymer from which the stent is made is dip coated onto the rod from either the melt or an appropriate solution, such as ethyl acetate or methylene chloride. Additionally, the formed tube may be heat treated to increase its crystallinity; for example, the tube may be heated at about 80°–100° C. for about 5 minutes. However, the crystallinity should remain low enough to allow low temperature expansion of the stent. The fabrication process is believed to orient both the polymer chains and any crystallites formed in the circumferential direction. The "oriented" tube may be processed by laser micromachining as described previously. The thermo-mechanical expansion process further increases the crystallinity, modulus, and strength of the material, and ultimately the strength of the stent.

Still another method for creating materials with oriented polymer chains and crystallites is to fabricate tubes from fibers dram from the materials described herein. Conventional drawing of fibers aligns the polymer chains and induced crystallites parallel to the direction of fiber length. This process can result in substantial increases in modulus and strength as compared with the non-oriented material. Unlike conventional fiber drawing for self-reinforced composites, fibers for this application would be processed with draw ratios of approximately 20 to 50% of the draw ratio that produced optimal strength and modulus. Fibers of this nature will achieve their optimal strength and modulus when they are expanded in situ, where they will receive the additional drawing. In this technique, fibers may be fabricated into a tube by conventional fiber winding techniques on appropriately sized mandrels, and bonded to make contiguous structures by either solvent vapor fusion, autoclave pressure, vacuum bag, or other conventional techniques. This phase of the processing should not alter the orientation of either the polymer chains or crystallites in the drawn fibers. It is believed that the fibers should be oriented circumferentially so the polymer molecular chains and crystallites are aligned in a similar fashion. Additionally, the formed tube may be heat treated to increase the crystallinity; for example, the tube may be heated at about 80°–100° C. for about 5 minutes. However, the crystallinity should remain low enough to allow expansion of the stent. As above, micromachining then may be performed to introduce any desired perforations.

The stent desirably may incorporate one or more drugs that positively affect healing at the site where the stent is deployed, either incorporated into the copolymer forming the stent, or incorporated into the coating, or both. Such drugs may include antithrombotics (such as anticoagulants), antimitogens, antimitotoxins, antisense oligonucleotides, gene therapy vehicles, nitric oxide, and growth factors and inhibitors. Direct thrombin inhibitors believed to be useful in the invention include Hirudin, Hirugen, Hirulog, PPACK (D-phenylalanyl-L-propyl-L-arginine chloromethyl ketone), Argatreban, and D-FPRCH$_2$Cl (D-phenylalanyl-L-propyl-L-arginyl chloromethyl ketone); indirect thrombin inhibitors include Heparin and Warfarin. Materials capable of β-particle emission also may be useful to inhibit neointima formation. These materials preferably are incorporated in quantities that permit desirable timed release as the stent and/or coating biodegrades. Thus, a stent such as that shown in FIG. 1 is believed to have a useful structural life of about 5–10 weeks, and remains in the body for about 6–9 months without showing major loss of structure. From this information, the quantities of drugs to be included in the copolymer matrix may be readily determined.

A stent prepared according to the present invention preferably also incorporates surface coatings or thin films (about 25 μm thick) designed to reduce the risk of thrombosis and to deliver bioactive agents. These include polymers such as poly(ethylene glycol), poly(vinyl alcohol), poly(vinyl pyrrolidone), poly(methacrylic acid), poly(acrylic acid), and polyacrylamide, that are blended or copolymerized with biodegradable materials; monomers of those materials also may be employed, as may other materials having similar lubricious effects. These materials may be formed as either statistical, block, or graft copolymers or as interpenetrating polymer networks. These materials may serve as drug delivery systems by incorporating effective quantities of pharmacologically active materials in the coating. The film may coat only the surfaces of the stent, or may extend over the micro-machined perforations in the stent to create a combination of a barrier and delivery vehicle.

In making stents according to the invention, it is desirable to control the glass-transition temperature by controlling the copolymer molar ratio and degree of crystallinity. Thus, a stent having lower crystallinity will exhibit a lower glass-transition temperature than with a stent having a higher degree of crystallinity. By controlling the degree of crystallinity, therefore, one may engineer a copolymer that exhibits optimal strain performance within the temperature range above body temperature but below temperatures that will injure tissue surrounding the body lumen in which the stent is to be deployed. As already noted, quenching the extruded hot stent tends to lock in an amorphous structure that desirably reduces the glass-transition temperature of the polymer. Likewise, the stents made according to the invention may be annealed at about 80°–90° C. to increase the crystallinity of the polymer and thereby increase the glass-transition temperature.

In the temperature range described above, the poly(L-lactide-ε-caprolactone) copolymer undergoes thermally-

assisted mechanical expansion when exposed to a balloon catheter that is heated in situ during percutaneous insertion of the stent. For example, a conventional balloon catheter used for percutaneous placement of a stent may be filled with a heated contrast medium (at a temperature sufficiently high to heat the stent) that can be injected into the balloon, providing in one medium a method both for expanding the balloon and for transferring heat into the stent. Thus, the contrast medium may be heated in situ using microwave radiation, an RF generator, or a resistance heater, and/or by injecting into the catheter contrast medium that has been heated externally of the body. The contrast medium will need to be heated to about 70° C. to permit sufficient heat to transfer to the stent, and the heated medium will be retained within or circulated through the catheter over a predetermined time period to permit the temperature of the stent to rise above the glass-transition temperature. Heated contrast medium is retained within or circulated through the catheter until the stent rises above the glass-transition temperature. Experimental data shows that sufficient heating occurs in a 37° C. water bath using a saline solution in place of a contrast medium, holding the saline solution at 60° C. for about three minutes.

Instead of a conventional balloon catheter, and depending upon the amount of time needed to heat the stent sufficiently to permit expansion, a perfusion catheter may be used so that the flow of fluids, such as blood, through the body lumen is not interrupted while the stent is being deployed. The perfusion catheter, by permitting blood flow through the affected region, also enhances convection cooling of the catheter and stent.

Thus, to deploy the stent according to the present invention, the stent is placed in its unexpanded state along the periphery of a balloon portion of a balloon catheter, and inserted into the body lumen percutaneously where it travels through the body lumen to the desired site for deployment. The location of the stent at the desired site may be confirmed intraoperatively by radiography. Once at the desired site, the stent is heated for the requisite period of time until its temperature is above the glass-transition temperature of the copolymer, and the balloon then is expanded so that the stent expands to the required size. The heat source then is removed, and the stent cooled by convection and conduction until its temperature is reduced below the glass-transition temperature. (Alternatively, but less desirably, a cooling medium may optionally be introduced through the catheter to cool the stent below the glass-transition temperature.) The stent may also be expanded slightly during this cooling process to fix the circumferential alignment of the polymer chains and prevent strain recovery (shrinkage) of the expanded stent.

One such heating technique is described generally in Lee, U.S. Pat. No. 5,292,321 (which is incorporated by reference herein). However, the positive cooling step required by Lee is not needed in the preferred embodiment of the present invention. Rather convection cooling resulting from blood flow past the stent, and the conduction of heat from the stent into surrounding body tissues, are believed adequate to return the stent to a temperature below the glass-transition temperature.

Another heating technique that may be used in the invention is described generally in Rappaport, U.S. Pat. No. 5,470,352 (which is incorporated by reference herein), as a balloon catheter including a microwave antenna. According to Rappaport, microwave energy first heats low water content materials, leaving high water content materials (such as body tissue) relatively unaffected. Because the stent made according to the invention is made from a low water content material, it will be heated preferentially by such a microwave antenna before body tissues are adversely affected. If such a heating technique is used, it may be desirable to modify the stent to include material enhancing the stent's absorption of microwave radiation.

Alternatively, the microwave frequency and power may be adjusted to preferentially heat the amorphous domains and disordered defects within the crystalline domains. The selective heating may be achieved by using an alternating current field with a high frequency in the microwave region (e.g., 2.45 GHz, 1.5 kW) in a manner known to the art. The advantage of this method of heating is that low temperature microwave heat-drawing is believed to produce similar physical properties at lower temperatures than the other methods described herein, since the amorphous domains are selectively targeted. As previously mentioned, it is believed that the expansion observed within the temperature range of about 38°–55° C. is due to the orientation of the polymer chains in the amorphous domains. This method is believed to allow deployment with minimal transfer of heat to the surrounding tissue, and avoids the need for positive cooling.

Another embodiment uses a balloon that is coated with a microwave sensitive material that selectively heats when exposed to microwave radiation. Heat transferred from this coating raises the temperature of the stent to permit thermomechanical expansion.

In still another embodiment, the balloon may be coated with a dye or similar substance that heats upon exposure to electromagnetic radiation (such as ultraviolet light), which is introduced through the catheter using an optical fiber to heat the stent in situ.

These embodiments reveal that the invention is not limited to a single method of deployment. Other heating and expansion methods besides those described may be used to carry out the invention in practice, however, it should be understood that the invention is limited to thermomechanical deployment techniques.

The present invention has been described with respect to one embodiment, which is not meant to and should not be construed to limit the invention. Those skilled in the art will understand that variations from the embodiments and conditions described herein may be made without departing from the invention as claimed in the appended claims.

What is claimed is:

1. An expandable, biodegradable stent for use within a body lumen comprising a hollow tube made from a copolymer of L-lactide and ϵ-caprolactone that, in unexpanded form, is of a first diameter sufficient to be retained upon a balloon catheter for placement within the body lumen, and that is not plastically expandable at normal body temperatures, and that is expandable using thermomechanical means at a temperature between about 38°–55° C. when the balloon catheter is inflated to a second diameter sufficient to be retained within the body lumen.

2. The stent of claim 1, wherein the molar ratio of L-lactide to ϵ-caprolactone is in the range from about 90:10 to about 98:2.

3. The stent of claim 1, wherein the tube is imperforate.

4. The stent of claim 1, wherein the tube is perforated, the perforations placed at a distance relative to each other corresponding to cell ingrowth within the body lumen.

5. The stent of claim 1, wherein the tube is nonwoven.

6. The stent of claim 1, wherein the tube incorporates a radio-opaque material.

7. The stent of claim 1, wherein the tube includes a drug blended with the copolymer.

8. The stent of claim 7, wherein the drug is selected from the group consisting of antithrombotics, anticoagulants, antimitogens, antimitotoxins, antisense oligonucleotides, gene therapy vehicles, nitric oxide, growth factors and inhibitors, Hirudin, Hirugen, Hirulog, PPACK, D-FPRCH$_2$Cl, Heparin, and Warfarin.

9. The stent of claim 1, wherein the tube is coated with a lubricious material.

10. The stent of claim 9, wherein the thickness of the coating is about 25 μm.

11. The stent of claim 9, wherein the coating is blended with a drug.

12. The stent of claim 11, wherein the drug is selected from the group consisting of antithrombotics, anticoagulants, antimitogens, antimitotoxins, antisense oligonucleotides, gene therapy vehicles, nitric oxide, growth factors and inhibitors, Hirudin, Hirugen, Hirulog, PPACK, D-FPRCH$_2$Cl, Heparin, and Warfarin.

13. The stent of claim 9, wherein the coating is a blend of a biodegradable material with lubricious materials selected from the group consisting of poly(ethylene glycol), poly (vinyl alcohol), poly(vinyl pyrrolidone), poly(acrylic acid), poly(methacrylic acid) and polyacrylamide.

14. The stent of claim 9, wherein the coating is a copolymer of a biodegradable material with lubricious materials selected from the group consisting of monomer constituents of poly(ethylene glycol), poly(vinyl alcohol), poly(vinyl pyrrolidone), poly(acrylic acid), poly(methacrylic acid) and polyacrylamide.

15. An expandable, biodegradable stent for use within a body lumen comprising a hollow tube made from a copolymer of L-lactide and ε-caprolactone that, in unexpanded form, is of a first diameter sufficient to be retained upon a balloon catheter for placement within the body lumen, and that is not plastically expandable at normal body temperatures, and that is expandable using thermo-mechanical means at a temperature between about 38°–55° C. when the balloon catheter is inflated to a second diameter sufficient to be retained within the body lumen, further comprising a lubricious coating.

16. The stent of claim 15, wherein the thickness of the coating is about 25 μm.

17. The stent of claim 15, wherein the coating is a blend of a biodegradable material with lubricious materials selected from the group consisting of poly(ethylene glycol), poly(vinyl alcohol), poly(vinyl pyrrolidone), poly(acrylic acid), poly(methacrylic acid) and polyacrylamide.

18. The stent of claim 15, wherein the coating is a copolymer of a biodegradable material with lubricious materials selected from the group consisting of monomer constituents of poly(ethylene glycol), poly(vinyl alcohol), poly (vinyl pyrrolidone), poly(acrylic acid), poly(methacrylic acid) and polyacrylamide.

19. The stent of claim 15, wherein the coating is blended with a drug.

20. The stent of claim 19, wherein the drug is selected from the group consisting of antithrombotics, anticoagulants, antimitogens, antimitotoxins, antisense oligonucleotides, gene therapy vehicles, nitric oxide, growth factors and inhibitors, Hirudin, Hirugen, Hirulog, PPACK, D-FPRCH$_2$Cl, Heparin, and Warfarin.

21. A method for making a stent comprising the steps of:

providing a copolymer of L-lactide and ε-caprolactone that is not expandable at normal body temperatures, and that is thermo-mechanically expandable at a temperature between about 38°–55° C.;

creating a tube from the copolymer having a diameter sufficient to permit the tube to be retained upon an unexpanded balloon catheter for insertion into a body lumen; and

cutting the tube into lengths for use as a stent within the body lumen.

22. The method of claim 21, wherein the tube is created by extrusion.

23. The method of claim 21, wherein the tube is created by dip-coating.

24. The method of making a stent of claim 21, wherein the ratio of L-lactide to ε-caprolactone is in the range from about 90:10 to about 98:2.

25. The method of making a stent of claim 21, further comprising the step of micromachining perforations in the tube using a laser.

26. The method of making a stent of claim 21, further comprising the step of incorporating radio-opaque material in the tube.

27. The method of making a stent of claim 21, further comprising the step of blending a drug with the copolymer.

28. The method of making a stent of claim 27, wherein the drug is selected from the group consisting of antithrombotics, anticoagulants, antimitogens, antimitotoxins, antisense oligonucleotides, gene therapy vehicles, nitric oxide, growth factors and inhibitors, Hirudin, Hirugen, Hirulog, PPACK, D-FPRCH$_2$Cl, Heparin, and Warfarin.

29. The method of making a stent of claim 21, further comprising the step of coating the stent with a lubricious material.

30. The method of making a stent of claim 29, further comprising the step of blending a drug with the coating.

31. The method of making a stent of claim 30, wherein the drug is selected from the group consisting of antithrombotics, anticoagulants, antimitogens, antimitotoxins, antisense oligonucleotides, gene therapy vehicles, nitric oxide, growth factors and inhibitors, Hirudin, Hirugen, Hirulog, PPACK, D-FPRCH$_2$Cl, Heparin, and Warfarin.

32. The method of making a stent of claim 29, wherein the coating is a blend of a biodegradable material with a lubricious materials selected from the group consisting of poly(ethylene glycol), poly(vinyl alcohol), poly(vinyl pyrrolidone), poly(methacrylic acid) and polyacrylamide.

33. The method of making a stent of claim 29, wherein the coating is a copolymer of a biodegradable material with a lubricious materials selected from the group consisting of monomer constituents of poly(ethylene glycol), poly(vinyl alcohol), poly(vinyl pyrrolidone), poly(methacrylic acid) and polyacrylamide.

34. A method for making a stent comprising the steps of:

providing a copolymer of L-lactide and ε-caprolactone that is not expandable at normal body temperatures, and that is thermo-mechanically expandable at a temperature between about 38°–55° C.;

creating a tube from the copolymer having a diameter sufficient to permit the tube to be retained upon an unexpanded balloon catheter for insertion into a body lumen;

cutting the tube into lengths for use as a stent within the body lumen; and,

thermo-mechanically expanding the stent within the body lumen to increase the hoop strength of the stent by a sufficient amount to substantially support the body lumen.

35. The method of making a stent of claim 34, wherein the stent is thermo-mechanically expanded so that the draw ratio of the expanded stent is greater than 2.0.

36. A method of deploying an expandable, biodegradable stent within a body lumen, comprising the steps of:

providing percutaneous access to the body lumen;

placing the unexpanded stent, in the form of an unexpanded hollow, nonwoven tube made from a copolymer of L-lactide and ϵ-caprolactone, upon a balloon portion of a balloon catheter;

transporting the stent to a desired location in the body lumen using the catheter;

heating the stent to a temperature between 38°–55° C., to permit thermo-mechanical expansion of the stent;

expanding the stent to a desired diameter by inflating the balloon catheter;

allowing the stent to cool at least below about 38° C. without applying any positive cooling;

deflating the balloon portion of the catheter; and,

withdrawing the catheter.

37. The method of deploying a stent of claim **36**, wherein the stent is heated by employing a heated material within the catheter to expand the balloon portion of the catheter.

38. The method of deploying a stent of claim **36**, wherein the stent is heated using a heating method selected from the group consisting of microwave heating, DC heating, RF heating, and heating using ultraviolet radiation.

39. The method of deploying a stent of claim **36**, wherein the stent is made from a copolymer having a ratio of L-lactide to ϵ-caprolactone in the range from about 90:10 to about 98:2.

40. The method of deploying a stent of claim **36**, wherein the stent is imperforate.

41. The method of deploying a stent of claim **36**, wherein the stent is perforated, the perforations placed at a distance relative to each other corresponding to cell ingrowth patterns within the body lumen.

42. The method of deploying a stent of claim **36**, wherein the stent is nonwoven.

43. The method of deploying a stent of claim **36**, wherein the stent includes a radio-opaque material.

44. The method of deploying a stent of claim **36**, wherein the stent includes a drug blended with the copolymer.

45. The method of deploying a stent of claim **44**, wherein the drug is selected from the group consisting of antithrombotics, anticoagulants, antimitogens, antimitotoxins, antisense oligonucleotides, gene therapy vehicles, nitric oxide, growth factors and inhibitors, Hirudin, Hirugen, Himlog, PPACK, D-FPRCH$_2$Cl, Heparin, and Warfarin.

46. The method of deploying a stent of claim **36**, wherein the stent is coated with a lubricious material.

47. The method of making a stent of claim **46**, further comprising the step of blending a drug with the coating.

48. The method of making a stent of claim **47**, wherein the drug is selected from the group consisting of antithrombotics, anticoagulants, antimitogens, antimitotoxins, antisense oligonucleotides, gene therapy vehicles, nitric oxide, growth factors and inhibitors, Hirudin, Hirugen, Hirulog, PPACK, D-FPRCH$_2$Cl, Heparin, and Warfarin.

49. The method of deploying a stent of claim **46**, wherein the coating is a blend of a biodegradable material with a lubricious materials selected from the group consisting of poly(ethylene glycol), poly(vinyl alcohol), poly(vinyl pyrrolidone), poly(methacrylic acid) and polyacrylamide.

50. The method of deploying a stent of claim **46**, wherein the coating is a copolymer of a biodegradable material with a lubricious materials selected from the group consisting of monomer constituents of poly(ethylene glycol), poly(vinyl alcohol), poly(vinyl pyrrolidone), poly(methacrylic acid) and polyacrylamide.

51. A method of deploying an expandable, biodegradable stent within a body lumen, comprising the steps of:

providing percutaneous access to the body lumen;

placing the unexpanded stent, in the form of an unexpanded hollow, nonwoven tube made from a copolymer of L-lactide and ϵ-caprolactone, upon a balloon portion of a balloon catheter;

transporting the stent to a desired location in the body lumen using the catheter;

heating the stent to a temperature between 38°–55° C., to permit thermo-mechanical expansion of the stent;

expanding the stent to a desired diameter by inflating the balloon catheter so that the draw ratio of the expanded stent is greater than 2.0;

allowing the stent to cool at least below about 38° C.;

deflating the balloon portion of the catheter; and,

withdrawing the catheter.

* * * * *

United States Patent [19]

Penny, III et al.

[11] **Patent Number: 4,816,029**

[45] **Date of Patent: Mar. 28, 1989**

[54] **STENT FOR AORTIC HEART VALVE**

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[73] Assignee: **Medtronic, Inc.**, Minneapolis, Minn.

[21] Appl. No.: **261,393**

[22] Filed: **May 7, 1981**

[51] **Int. Cl.**[4] **A61F 2/24**

[52] **U.S. Cl.** **623/2**; 623/900

[58] **Field of Search** 3/1.5, 1; 623/2, 900

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,570,014	3/1971	Hancock	3/1.5
3,755,823	9/1973	Hancock	3/1.5
3,983,581	10/1976	Angell et al.	3/1.5
4,035,849	7/1977	Angell et al.	3/1.5
4,084,268	4/1978	Ionescu et al.	3/1.5
4,106,129	8/1978	Carpentier et al.	3/1.5
4,172,295	10/1979	Batten	3/1.5
4,222,126	9/1979	Boretos et al.	3/1.5

Primary Examiner—Ronald L. Frinks

Attorney, Agent, or Firm—Joseph F. Breimayer; John L. Rooney; Robert J. Klepinski

[57] **ABSTRACT**

A plastic stent for a prosthetic trileaflet heart valve consisting of a cylindrical body portion terminating at one end in three apical, spaced commissure posts, and at the other end, in a skirt comprising three arcuate extensions, each extension being provided with an interrupted channel adjacent the outer edge thereof. An optional metal ring may be mounted over the skirt adjacent the body portion. A cloth cover is secured to the stent by stitching directly through the skirt in the area of reduced thickness resulting from the interrupted channel.

16 Claims, 1 Drawing Sheet

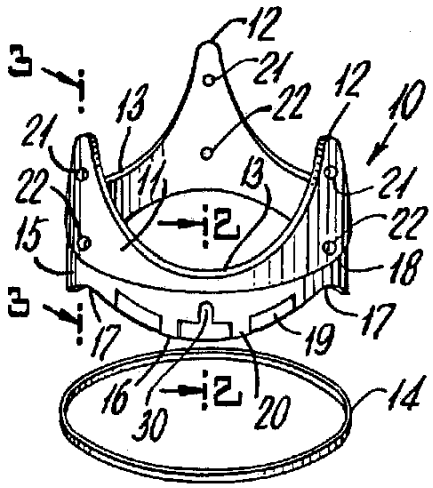


Fig.1.

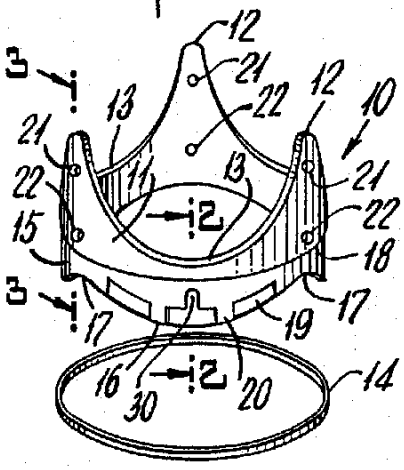


Fig.2.

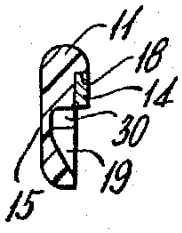


Fig.3.

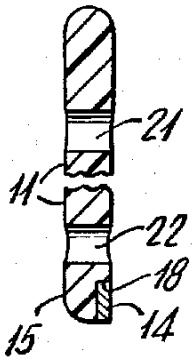


Fig.4.

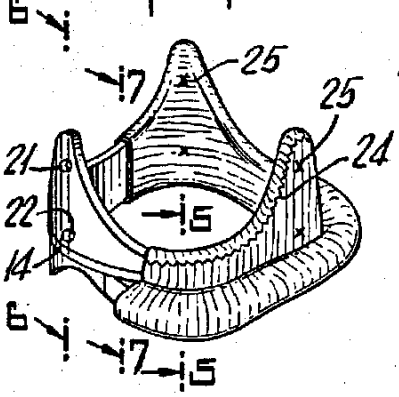


Fig.6.

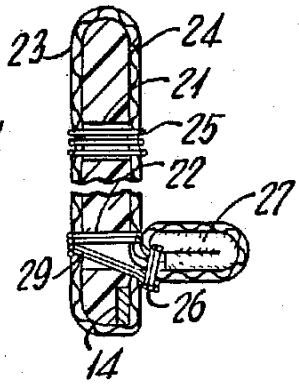


Fig.7.

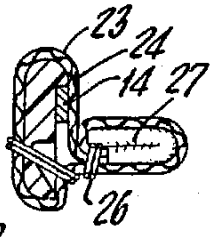


Fig.8.

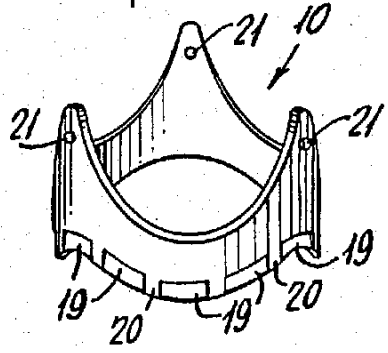
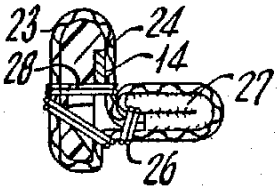


Fig.5.



STENT FOR AORTIC HEART VALVE

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to a polymeric framework or stent for mounting a trileaflet heart valve constructed of natural or synthetic materials, particularly for aortic valve replacement.

2. Description of Prior Art

Frame-mounted, trileaflet heart valves have been widely used for many years as a prosthetic replacement for defective aortic valves in humans. Natural tissue valves have been constructed by mounting gluteraldehyde-fixed porcine heart valves in a suitable framework or stent as described, for example, in U.S. Pat. Nos. 3,570,014, 3,755,823, 3,983,581 and 4,035,849. Similar trileaflet valves have been constructed from autologous and hemologous fascia lata and dura matter, and from heterologous pericardium mounted in a suitable stent as described, for example, in U.S. Pat. Nos. 4,084,268 and 4,172,295.

More recently, efforts have been directed to the development of totally synthetic trileaflet heart valves constructed from tubes and films of biocompatible polymers such as polyurethane. Such valves are also mounted in a stent as described, for example, in U.S. Pat. No. 4,222,126.

Valve stents of the prior art have been constructed of noncorrosive metals such as stainless steel and of plastic such as polypropylene or polyethylene. Plastic stents for porcine valves as described in U.S. Pat. Nos. 3,570,014 and 3,755,823 have an intricate design which requires fabrication by machining from a solid block of polymer at great expense. Plastic stents as described in U.S. Pat. Nos. 3,983,581 and 4,035,849 are of a simpler design and may be formed by injection molding. While such stents are inexpensive, it is somewhat difficult to attach the cloth cover with the recommended method of heat lamination.

It is accordingly an object of the present invention to provide an improved stent for mounting a porcine heart valve.

It is another object of this invention to provide a stent for mounting a trileaflet heart valve wherein the leaflets are constructed of natural or synthetic sheet materials.

It is a further object of this invention to provide a stent for a prosthetic heart valve intended for use in the aortic position.

It is a yet further object of this invention to provide an improved heart valve stent which may be injection-molded and still permit a cloth cover to be attached by stitching.

These and other objects of the present invention will be apparent from the ensuing description and claims.

SUMMARY OF THE INVENTION

This invention is directed to an improved design and construction of a heart valve stent particularly adapted for use in constructing a prosthetic, aortic heart valve utilizing natural or synthetic material. The stent itself is injection-molded of a suitable biocompatible, polymeric material such as polypropylene or polyethylene.

The stent has a cylindrical upper body portion comprising three circumferentially-spaced, axially-extending apical commissure posts or struts interconnected by valleys. The lower portion of the stent forms a skirt comprising three depending arcuate extensions in registry with the valleys of the upper portion. The arcuate extensions are interconnected by arches in registry with the commissure posts of the upper portion. The upper and lower portions of the stent together define a unitary, sculptured, open cylinder having inner and outer surfaces.

Each arcuate extension of the skirt is provided with an edge channel adjacent the lower edge thereof over a major portion of the perimeter of the extension. A side channel centrally disposed in each arcuate extension extends from the edge channel toward the upper body portion of the stent. The edge channels are characterized by having a lower side wall which angles from the base of the channel to the outer edge of the skirt.

The reduced wall thickness of the skirt in the area of the channel is readily pierced by a surgical needle and permits a cloth cover to be attached directly to the stent by stitching through this area. Since the sewing thread actually pierces the stent rather than merely being looped around an arm or strut, or being passed through preexisting holes as in prior art designs, the thread may be precisely placed, and there is no possibility of the cloth cover slipping or being displaced relative to the stent during the stitching procedure.

The lower skirt portion of the stent preferably has a thinner wall and smaller outside diameter than the upper body portion of the stent, thereby creating a circumferential ledge in the outer wall at the line of juncture between the skirt and body portions. The stent may be circumferentially reinforced and made radiopaque if desired with a metal ring fitted about the outside of the skirt adjacent the ledge formed by the upper portion. Preferably, the thickness of the ring conforms to the width of the ledge so that the outside surface of the ring is substantially a continuation of the outside surface of the upper portion of the stent. When the cloth cover and sewing cushion are attached to the stent, the metal ring is fully covered and securely fixed in place.

DRAWINGS

FIG. 1 is a view in perspective of the heart valve stent of the present invention with the metal reinforcing ring shown separately for clarity of illustration.

FIG. 2 is a view in cross-section taken along line 2—2 of FIG. 1.

FIG. 3 is another view in cross-section taken along line 3—3 of FIG. 1.

FIG. 4 is a view in perspective of a covered stent of FIG. 1 including the metal ring and with the cloth cover and sewing cushion shown in partial section.

FIG. 5 is a view in cross-section taken along line 5—5 of FIG. 4.

FIG. 6 is a view in cross-section taken along line 6—6 of FIG. 4 and through a commissure post of the stent.

FIG. 7 is a view in cross-section taken along line 7—7 of FIG. 4 at a point midway between FIGS. 5 and 6.

FIG. 8 is a view in perspective of a heart valve stent of the present invention without the optional metal reinforcing ring.

DESCRIPTION OF INVENTION

Referring now to FIG. 1, there is illustrated a plastic stent 10 according to the present invention, including an optional metal reinforcing ring 14. The stent consists of a cylindrical upper body portion 11 terminating in three axially-extending, commissure posts 12 interconnected

by valleys 13 defining a deeply scalloped configuration. The lower skirt portion 15 of the stent is formed by three dependent arcuate extensions 16 interconnected by arches 17. The arcuate extensions are in registry with the valleys of the upper portion while the interconnecting arches are in registry with the commissure posts.

In a preferred embodiment as illustrated in FIG. 1, the outside diameter of the skirt is smaller than the outside diameter of the body portion of the stent thereby creating a circumferential step or ledge 18 in the outer surface of the stent along the line of juncture of the body and skirt portions. Metal ring 14 is sized to fit snugly around the outside of the skirt abutting the upper body portion, and the outer diameter of the metal ring is substantially the same as that of the body portion of the stent so that when in place, the metal ring forms an extension of the outer wall of the body portion of the stent. FIG. 2 is a view in cross section through the stent midway between two commissure posts showing the position of the ring relative to the circumferential ledge of the stent. FIG. 3 is a similar view in cross section through a commissure post.

With further reference to FIG. 1, the skirt is provided with channels 19 traversing the lower edge of the depending arcuate extensions over a major portion of the length thereof. These channels may be continuous over the length of the arcuate extension or interrupted by axially-extending reinforcing ribs 20 as illustrated in FIG. 1. Each arcuate extension includes a centrally disposed side channel 30 extending from the edge channel toward ledge 18, the distance between the blind end of channel 30 and ledge 18 being no greater than the width of ring 14.

Edge channels 19 are configured as best illustrated in the cross-sectional views of FIGS. 2 and 7 where the channel is seen to have a lower side wall angled toward the edge of the arcuate extension. The upper side wall of the channel is substantially perpendicular to the outside surface of the skirt, and the base of the channel is preferably concave as illustrated to form a continuous curve with the side walls. The side channel 30 extends from the base of the edge channel, and the walls of the side channel may be substantially perpendicular to the outside surface of the skirt.

The stent of the present invention is further provided with a first opening 21 in the apical portion of each commissure post, and a second opening 22 in the base of each commissure post proximal to step 18. These openings can be molded, but are preferably drilled and deburred in a separate operation after molding.

The stent of FIG. 1 is prepared for use in mounting a heart valve by adding a cloth cover and a sewing cushion as illustrated in FIGS. 4 through 7. FIG. 4 is a view in perspective of the stent of FIG. 1 with the cloth cover and sewing cushion in place and illustrated in partial section. Cloth cover 23 is constructed of an inner section and an outer section joined at seam 24 which is positioned on the outer surface of the stent to avoid contact with the leaflets of the valve. The cloth cover is secured to the commissure posts by stitching 25 through hole 21 as illustrated in FIG. 6.

The inner section of the cloth cover is brought through the base of the stent and around the bottom of the skirt. Stitching through channels 19 in the skirt secure the cloth cover at the base of the stent body as illustrated in FIGS. 5 and 7. Additional stitching through hole 22 in the body portion of the stent secures the cloth at the base of the commissure post and also secures the metal ring in place as illustrated in FIG. 6. An additional stitch 28 through side channel 30 taken immediately below ring 14 as illustrated in FIG. 5 further secures the ring and tacks the outer cloth cover in place. A similar tacking stitch 29 placed through hole 22 is seen in FIG. 6.

The fabric from the inner cover extends from the skirt to encircle sewing cushion 27 which may be a washer of an elastomeric material such as silicone rubber or a torus formed from a rolled or folded tube of fabric such as a polyester double-knit velour. The edge of the inner cover is folded under and stitched at 26 to secure the sewing ring and edge of the outer cover as illustrated in FIGS. 5 through 7. It will be noted that the sewing cushion follows the contour of the arcuate extensions of the skirt as illustrated in FIG. 4, and the position of the sewing cushion relative to the metal ring varies as illustrated in FIGS. 5 through 7.

The channels in the skirt around the base of the stent are an essential feature of the present invention in regard to both functional and economic considerations. The channels permit the cloth cover to be stitched directly to the stent in a positive and reliable manner. The thickness of the skirt in the area of the base of the channel is sufficiently thin to provide minimal resistance to stitching with a surgical needle, and yet the use of a channel rather than an open slot provides support for the cloth and the stitching. Stitching through the base of the channel assures the stability of the stitch and the cloth covering providing a definite functional advantage. The unique shape of the channel, particularly the angled lower side wall, permits the stent to be injection molded with a simple, one-piece mold. When the stent is removed from the mold, the angled channel side wall acts as a cam surface to deflect the bottom edge of the skirt inward and thereby permit passage of the skirt over the protuberances of the mold which form the channels. The economic advantage of the stent accordingly results from a simplified method of manufacture as compared to machined stents or stents requiring compound molds.

The stents of the present invention are preferably injection-molded of polypropylene or other suitable biocompatible thermoplastic polymeric material. Polypropylene is particularly preferred because it is readily molded, has good strength, and has a moderate degree of flexibility which is desirable to relieve stresses on the stent and the valve material during use. Other suitable materials include Delrin polymer (a polyformaldehyde of greater than 15,000 molecular weight sold by DuPont), Lexan polymer (a polycarbonate), nylon (a hexamethylene diamine-adipic acid polymer) and high density polyethylene. The molded stents are desirably annealed to relieve internal stress and subsequently polished and inspected before covering with cloth. Polypropylene stents may be suitably annealed by heating in an oven at about 90° C. for 20 minutes.

While the preceding description has been directed to a stent which incorporates a metal reinforcing ring, this ring is optional as explained above. If the ring is to be omitted, the stent may be of uniform wall thickness throughout and the step or offset between the upper and lower portion eliminated as illustrated in FIG. 8. In this case, channels 19 preferably extend continuously around the edge of the skirt interrupted only by spaced reinforcing ribs 20. The channels are necessarily deeper due to the greater wall thickness, but the general configuration of the channels is as previously described. Since

no ring is present, the side channels previously described are not included in the stent of FIG. 8.

The reinforcing ribs interrupting the channel are preferably equiangularly spaced at 15 to 60° intervals, and preferably at 30° intervals resulting in 12 ribs for the continuous channel illustrated in FIG. 8.

Typical stents for use in the aortic positions in humans have a nominal inside diameter of 16 to 26 mm. When molded of polypropylene, the thickness of the body of the stent is suitably at least about 1.0 mm, and preferably from about 1.0 to 1.5 mm; the skirt is at least about 0.5 mm, and preferably from about 0.5 to 1.5 mm; and the base of the channel is less than about 0.2 mm, and preferably from about 0.1 to 0.15 mm. The step or offset between the upper body of the stent and the skirt is suitably about 0.5 mm wide to accommodate the metal reinforcing ring which is typically 1.0 mm high by 0.5 mm thick. The valve is proportioned approximately according to its nominal size with the maximum axial dimension of the apical, commissure posts of the upper body section being approximately equal to one-half the inside radius of this section, and the minimum axial dimension of the valleys between commissure posts being from about 0.5 to 1.0 mm. The drilled holes in each commissure post are suitably about 0.9 mm in diameter.

The stents of the present invention can be used with good results to mount heart valves of natural or synthetic materials. Natural materials include, without limitation, standard porcine heart valves, modified porcine heart valves as where the leaflet with the septal shelf is replaced with a leaflet from another valve, and natural tissue valves wherein the three cusps of the valve are formed from three separate pieces of pericardial or fascia lata tissue. Synthetic materials include, without limitation, rubberized fabrics, polyurethane film, and one-piece molded polyurethane valves. Rubberized fabric and polyurethane film are utilized in valve construction by forming the three cusps of the valve from separate pieces of material or from a single tubular section. Conventional manufacturing procedures in forming the valve may be followed in all cases.

We claim:

1. A stent for mounting a trileaflet heart valve comprising an upper body portion and a lower skirt portion together defining a unitary, sculptured, open cylinder having inner and outer surfaces,

said body portion comprising three circumferentially-spaced, axially-extending, apical commissure posts interconnected by valleys,

said skirt portion comprising three depending arcuate extensions in registry with the valleys of said body portion,

and a channel traversing the perimeter of said skirt adjacent the lower edge of said arcuate extension, said edge channel being interrupted by a plurality of spaced, axially-oriented reinforcing ribs traversing said channel.

2. The stent of claim **1** wherein said ribs are equiangularly spaced around the circumference of said stent at 15 to 60° intervals.

3. The stent of claim **1** wherein said ribs are equiangularly spaced at 30° intervals.

4. A stent for mounting a trileaflet heart valve comprising a body portion and a skirt portion defining a unitary, sculptured, open cylinder having inner and outer surfaces,

said body portion comprising three circumferentially-spaced, axially-extending apical commissure posts interconnected by valleys,

said skirt portion comprising three depending arcuate extensions in registry with the valleys of said body portion, the wall thickness of said skirt portion being less then that of said body portion, and the outer surface of said stent including a circumferential step at the juncture of said body and skirt portions corresponding to the difference in wall thickness,

and an edge channel traversing the perimeter of said skirt adjacent the edge of said arcuate extensions.

5. The stent of claim **4** wherein the arcuate extensions of said skirt portion are interconnected by arches in registry with the commissure posts of said body portion.

6. The stent of claim **5** wherein said edge channel in each of said arcuate extensions terminates at the arches interconnecting said arcuate extensions.

7. The stent of claim **5** wherein each of said arcuate extensions additionally includes a centrally disposed side channel extending axially toward said circumferential step from said edge channel of said skirt.

8. The stent of claim **4** wherein said edge channel includes a first side wall, a base and an opposing side wall, said first side wall extending at an angle from the edge of said arcuate extension to the base of said channel, said opposing side wall being perpendicular to the surface of said skirt, whereby the width of the channel at its base is substantially less than at the surface of said skirt.

9. The stent of claim **8** wherein the base of said channel is concave and forms a substantially continuous curve with said side walls.

10. The stent of claim **7** wherein said side channel has walls substantially perpendicular to the outer surface of said skirt.

11. The stent of claim **4** additionally including a metal ring circumscribing said skirt portion adjacent said circumferential step in the outer surface of said stent.

12. The stent of claim **6** wherein said edge channel in each of said arcuate extensions is interrupted by reinforcing ribs extending through said channel.

13. The stent of claim **12** having two uniformly-spaced axially-oriented ribs extending through the channel of each of said arcuate extensions.

14. The stent of claim **4** fabricated of polypropylene.

15. The stent of claim **14** wherein the wall thickness of said body portion is from 1.0 to 1.5 mm, and the wall thickness of said skirt portion is about 0.5 mm less than that of said body portion.

16. The stent of claim **14** wherein the wall thickness of the base of said edge channel is less than about 0.2 mm.

* * * * *

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EXAMINER	
NGUYEN VI X	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 03/03/2006

4/3/06; docketed
6/3/06
9/3/06

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/037,036	STINSON, JONATHAN S	
	Examiner	Art Unit	
	Victor X. Nguyen	3731	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2005*

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1 ☐ Certified copies of the priority documents have been received.

2 ☐ Certified copies of the priority documents have been received in Application No. _____

3 ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

1. Applicant's Appeal Brief filed 2/17/2005, with respect to claims 1-23 are acknowledged Therefore, the Final Office Action has been withdrawn However, upon further consideration, restriction to one of the following inventions is required under 35 U S C 121:

I Claims 1-12 and 15-23, drawn to a process for forming a stent of a polymer material, classified in class 264, subclass 235

II Claims 13-14, drawn to a thermoplastic polymer stent, classified in class 623, subclass 1 38

The inventions are distinct, each from the other because of the following reasons:

2 Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process (MPEP § 806 05(e)). In this case the process as claimed can be used to practice another and materially different apparatus, such as an apparatus that does not need a thermoplastic polymer stent having a hoopwise molecular orientation. For example the stent can have any shape including, but not limited to a hoopwise orientation such as polygons (i e , squares, rectangles and diamonds). The method of invention I does not recite steps necessitating the need for annealing the expanded diameter stent to shrink its diameter to a reduced diameter, and therefore is not limited to be performed by the apparatus of invention II. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X. Nguyen whose telephone number is (571) 272-4699. The examiner can normally be reached on M-F (8-4:30 P.M.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Victor X. Nguyen
Examiner
Art Unit 3731

Vn VN
2/28/2006

Julian W. Woo

JULIAN W. WOO
PRIMARY EXAMINER